AD_____

Award Number: DAMD17-98-1-8306

TITLE: Facilitating Breast Cancer Genetic Couseling through Information, Preparation and Referral: A Pilot Program Using the Cancer Information Service

PRINCIPAL INVESTIGATOR: Suzanne M. Miller, Ph.D.

CONTRACTING ORGANIZATION: Fox Chase Cancer Center
Philadelphia, Pennsylvania 19111

REPORT DATE: July 2000

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	July 2000	Annual (8 Jun 99 - 7 Jun 00)

4. TITLE AND SUBTITLE
Facilitating Breast Cancer Genetic Couseling through Information, Preparation and Referral: A Pilot Program Using the Cancer Information Service

5. FUNDING NUMBERS
DAMD17-98-1-8306

6. AUTHOR(S)
Suzanne M. Miller, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Fox Chase Cancer Center
Philadelphia, Pennsylvania 19111

E-MAIL:
s_robinson@fccc.edu

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 Words)*

Previous research has shown that women often lack knowledge regarding the kinds of information that are required to determine inherited risk as well as on the process and content of risk assessment/genetic testing. This lack of information leads them to feel unprepared for risk assessment/genetic testing, if they choose to seek it. The present study will evaluate an enhanced intervention's ability to increase a woman's knowledge of: 1) the factors that determine genetic predisposition to breast/ovarian cancer, 2) their personal family history and other risk factors, 3) the benefits and drawbacks of genetic testing for breast/ovarian cancer, 4) the range of surveillance and preventive behaviors available, and 5) the actual process of risk assessment/genetic testing. Participants are 200 women who contact the Cancer Information Service (CIS) requesting information on inheritable breast/ovarian cancer, risk assessment and/or genetic testing. Women are randomly assigned to either the standard or enhanced intervention. A randomized study in which the two interventions are compared will test the effectiveness of the CIS in increasing women's knowledge of inheritable breast/ovarian cancer and the process of risk assessment/genetic testing.

14. SUBJECT TERMS	15. NUMBER OF PAGES
Breast Cancer	88
	16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

( ) Where copyrighted material is quoted, permission has been obtained to use such material.

( ) Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

( ) Citations of commercial organizations and trade names in this report do not constitute an official Department of the Army endorsement or approval of the products or services of these organizations.

( ) In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

(✓) For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 32 CFR 219 and 45 CFR 46.

( ) In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Insitutes of Health.

J. M. Miller
Principal Investigator's Signature

6/28/00
Date

TABLE OF CONTENTS

Introduction

Previous research has shown that women often lack knowledge regarding the kinds of information that are required to determine inherited risk as well as on the process and content of risk assessment/genetic testing. This lack of information leads them to feel unprepared for risk assessment/genetic testing, if they choose to seek it. This pilot study will develop an enhanced intervention, from material gathered during focus groups and structured interviews, to increase a woman's knowledge of: 1) the factors that determine a genetic predisposition to breast/ovarian cancer, 2) personal family history and other risk factors, 3) the benefits and drawbacks of genetic testing for breast/ovarian cancer, 4) the range of surveillance and preventive behaviors available, and 5) the actual process of risk assessment/genetic testing. The intervention will be guided by the leading "information processing" theory, the Cognitive-Social Health Information Processing Model (C-SHIP). Participants are 200 women who contact the Atlantic Region of the National Cancer Institute's (NCI) Cancer Information Service (CIS) requesting information on inherited breast/ovarian cancer as well as those women calling specifically for information about risk assessment services and genetic testing. Women are randomly assigned to either the standard intervention or the enhanced intervention. A randomized study in which the standard intervention is being compared to the enhanced intervention will test the effectiveness of the CIS in increasing a woman's knowledge of inherited breast/ovarian cancer and the process of risk assessment/genetic testing.

Body

The identification of specific genes that predispose individuals and families to certain cancers is a milestone in medical research. Understanding the genetic basis of inherited cancers may lead to new approaches to treating and even preventing disease. For those in the general population who perceive themselves to be at risk, however, the identification of these cancer causing genes is as unsettling and unnerving as it is exciting and fraught with possibilities. The recent developments in cancer genetics, particularly the identification of the BRCA 1 and BRCA 2 genes, were highly publicized and created a demand for genetic information and counseling. A review of articles dating from 1994 shows a growing interest in providing risk assessment, information, education and counseling about genetic risk and testing, options for 'at risk' individuals and surveillance recommendations for non-affected persons. Although public awareness has increased, women may not have the information they need and are likely to overestimate their risk for inherited disease. (Iglehart, Miron et al. 1998) This project is designed to identify and address the needs of women who have concerns about their genetic risks for breast/ovarian cancers. In addition, for those women who intend to pursue high risk counseling and/or genetic testing, the pilot aims to educate and prepare them for what will more than likely be a lengthy process.

CIS Approval Process

The start date for accruing subjects to this project (October 18, 1999) coincided with the start of a new contract for this regional CIS office (October 15, 1999). With the new contract came a new name, *The Atlantic Region Cancer Information Service*, additional territory (we now serve all of Pennsylvania, New Jersey and Delaware) and new procedures for gaining approval for

research initiatives through the Cancer Information Service Branch (CISB) at the National Cancer Institute. The CIS research review process consists of several phases. A concept review, performed by the Project Officer at CISB, is the first step in gaining approval to continue project planning. To gain approval, projects must, among other things, be conducted with experienced investigators and fit in with the CIS research model and NCI priorities. The next step, a pre-grant submission review, is done to obtain final approval from CISB. Because this study began prior to the institution of the new CIS research review process, these first steps were approved retroactively. What will be forthcoming, however, is a designated milestone review to report on any problems or issues encountered and to brainstorm potential solutions. Finally, a finished project written report will be required at the end of the study to summarize results, lessons learned and plans for publication and presentation.

External Advisory Board

On October 5, 1999, a project advisory committee, comprised of national and regional experts in breast cancer genetics, genetic testing and risk assessment met to review the draft interventions and promotional materials (see Appendix 1 for a list of Advisors). Project staff presented an overview of the study, including results from the formative evaluation period, and solicited the committee's recommendations for any modification(s) of the proposed interventions and promotional fliers/brochures. Advisory Committee members, who had received drafts of the interventions and informed consent prior to the meeting, offered thoughtful and insightful reviews of the materials. We incorporated many of their suggestions into a revised protocol. For example, the Committee advised streamlining the Informed Consent so that it read more easily and consistently (see Appendix 2). Incorporating the Lerman Worry Scale gave valid measures of a woman's sense of distress at the prospect of getting breast or ovarian cancer as well as how much that prospect impinges on her daily life. In addition, we included several of the Committee's recommendations regarding layout and content in the final versions of the interventions (see Appendices 3 & 4).

Committee members offered advice on promotional materials as well as the interventions. As a result, we modified the language to focus on recruiting only those women calling about their personal risk for inherited disease and/or risk assessment services (Appendices 5 & 6). We believe that having the benefit of expert advice strengthened, enhanced and validated the study instruments. Their keen observations and perceptions were invaluable in helping us refine and sharpen the interventions and promotional materials.

Training Implementation & Evaluation

This past year has given us important insights into the complexities surrounding the development of staff training, implementation, and evaluation. Given the difficulty of the subject matter, multiple trainings were developed. They included sessions on basic genetics, cancer patterns and risk assessment, genetic counseling, genetic testing and informed consent, and understanding health behaviors. A separate session covered study logistics and familiarity with the computerized versions of the intervention. The training was completed over a 4-month period and subject matter experts conducted three of the sessions. Several of the resources that were initially identified and reviewed were also incorporated into the training. These resources served

to reinforce specific concepts and made the training more interactive and interesting for the staff. For example, video clips profiling the personal journeys of individuals and families confronting questions about genetic testing were included in the training on risk assessment and risk perception.

To evaluate the training, we developed pre- and post- tests to measure staff knowledge and attitude. There were 5 consistent knowledge questions and 2 attitudinal questions on both the pre and post- tests that were used for evaluation. The post-test also included 2 questions related to an interpretive exercise that measured the Information Specialists' ability to apply knowledge gained during training.

A particular challenge in the management of this project, from a training perspective, was the fact that the interventions for the study were conceptualized but not fully developed before the training was designed. The development of the intervention was quite laborious and time-consuming. However, the study timeline could not be adjusted further to delay the start of the initial training on background and content. The training had to be specific enough to meet the overall objectives for the study while providing flexibility in adding content as the interventions were completed. This evolution of the training curriculum created limitations to the scope of pre & post evaluations. One method by which to measure the success of training in enhancing staff's knowledge, skill, confidence, and comfort level was to examine the evaluation process and outcomes.

The purpose of the pre-test was twofold. We wanted to identify the gaps in staff knowledge (particularly in the areas of genetics, cancer patterns and risk, genetic testing, and the characteristics of the BRCA-associated mutations) as well as to design the training. The pre-test indicated gaps in these areas and a lack of staff confidence in their ability to provide such complex information to callers. While this information provided us with a basic training outline, additional training content was added over time as the interventions took shape. Once all of the training sessions were completed, a quantitative post-test was given (Appendix 7).

Other factors that limited the pre- & post- test evaluation results included some staffing issues that arose between the project's inception and the completion of training. For example, shortly after the pre-test was given, one Information Specialist resigned. Two other staff members were on maternity leave at varying times throughout the project. These issues were factored into the data analysis process.

Post test analysis demonstrated modest increases on questions related to cancer patterns, BRCA-associated mutations, and the risk associated with the presence of a known mutation. The other knowledge questions addressed genetics and the complexities associated with genetic testing. While the results showed no overall increase in knowledge on these questions, we believe that this may be more representative of the level of difficulty of the subject matter rather than a reflection of the training itself. The post-test interpretive exercise provided the most relevant information in terms of increased knowledge and understanding. Based on a given family history, Information Specialists were asked to construct a matching pedigree and answer 2 related questions. Staff was able to complete the pedigree with 100% accuracy. In addition,

91% were able to identify the emerging inheritance pattern correctly while 82% were able to indicate which family members would be appropriate candidates for genetic testing.

While improving Information Specialists' knowledge and understanding of the subject matter was a training priority, increasing staff's skills and comfort levels were equally important. When asked to describe their skill level and ability to explain the relationship between gene mutations and cancer to callers, a significant change was noted between the pre and post-test. Prior to training, only 18% of the staff felt very capable, 64% felt somewhat capable, and 18% indicated that they felt not at all capable. After training, 55% responded that they felt very capable and 46% were somewhat capable. After completing the training, no Information Specialist felt completely incapable of performing this task. Similarly, when the Information Specialists were asked to rate their skills in explaining issues related to gene testing to callers, their post-test scores were notably higher. Before training, only 9% of the Information Specialists felt that they were very capable at this task, whereas 36% said that they were somewhat capable and felt that they could perform this task without assistance and 55% said that they were not at all capable and would need assistance. After training, 36% indicated that they were now very capable of performing this task and 64% felt that they were somewhat capable and could perform this task without assistance. Once again, there was no staff member who felt completely incapable or that they would still need assistance when performing this task.

All performance and quality assurance activities completed since the training have confirmed these findings. During call monitoring, Information Specialists were noticeably more confident when providing information to participants and demonstrated skill in answering additional questions posed during the call. It is clear that training has been successful in closing many of the gaps that staff initially had and in enhancing their comfort levels in dealing with this subject matter.

Training Modifications for New Staff

The original training curriculum was developed in such a way so as to address any and all topics that potentially would be part of the final interventions and consisted of 8 sessions. Too, it was designed for staff who were already familiar with a lot of the material. Training for Information Specialists who were hired after the initial training, however, needed to be modified to allow incorporation into a 4-week certification training and to assure competence in conducting the study while focusing only on those areas covered in the interventions. Training was therefore reviewed and modified so that all new staff were adequately educated and prepared for this project. Most of the topics covered in the initial training are still covered in the revised curriculum, but in less detail and, with the exception of a session with a genetic counselor, without the benefit of subject matter specialists. A revised, skill-based training now includes sessions on cancer patterns, risk assessment and perception, informed consent, genetic testing and the associated psychological issues, and study logistics including familiarity with the computerized version of the intervention (Appendix 8).

Different modifications to the training were necessary in November 1999 when two Information Specialists transferred from another CIS office to the Atlantic regional office. Both were experienced Information Specialists who had been with the CIS for more than 6 years. To assess

their knowledge and comfort on the topic, a separate pre-test was developed. Subsequent changes to the modified version of the training were made in order to meet their particular needs. Regardless of the modifications made, all new staff receive a training workbook, handouts, and a series of job aids. We have trained 7 new Information Specialists using the modified training. In subsequent evaluation via call monitoring and observation, all staff who have joined the CIS since the project's inception and who have taken calls for the project have performed well with modified training.

Final Interventions

The final versions of the study interventions reflect content gathered from both the first year of formative evaluation of this project (which included focus groups and structured interviews with genetic counseling professionals, women at actual and/or perceived high risk and women in the general population) as well as National Cancer Institute and American Cancer Society publications. Guided by the Cognitive-Social Health Information Processing (C-SHIP) model (Miller, et.al., 1996, 1998), the interventions address participants' encoding perceptions, beliefs and expectancies, affect and knowledge-based self-regulatory processes.
The standard intervention includes the following components

- Self reported perceptions about risks for breast and ovarian cancers
- Questions from the Lerman Worry Scale and the Breast Cancer Knowledge Scale (Lerman, et.al., 1994. Ondrusek, et.al., 1999.)
- Education about known risk factors for breast cancer
- Discussion about patterns of inheritance
- Referrals to high-risk programs in their areas, if the women would like them. (Those who request referrals are given them orally over the telephone and also are sent information about regional programs along with the standard literature.)
- Finally, women are asked about their current screening practices and demographic information.

The enhanced intervention includes all of the above and, in addition

- Information about the hallmarks of inherited disease
- Specialists elicit a detailed family cancer history to be shared with the woman's primary health care provider.
- Women are also asked their knowledge and perceptions about the process, content and services involved in a formal risk assessment and genetic testing program, then educated about that which they did not mention.

Participants in both groups are sent the same NCI publications and factsheets. Those in the enhanced group are sent an additional publication, Understanding Gene Testing, as part of the randomization. (Appendix 9 delineates the content and follow-up for each group.) The interventions can take anywhere from 15 to 20 minutes, depending on the randomization and whether or not the woman has many questions. In fact, many of the calls have lasted longer than ½ hour because of the interaction between Specialist and caller.

Final Follow-up Interviews

Three follow-up interviews are conducted over the telephone at two weeks, two months, and six months post-baseline intervention (Appendices 10 & 11). Data collected at all follow-up

timepoints include: risk perceptions, cancer specific worry, advantages/disadvantages to pursuing risk assessment, knowledge, intention to seek and preparedness to pursue risk assessment, performance of screening behaviors, and satisfaction with the Cancer Information Service (CIS). In addition, attentional style and actual risk are measured at the two-week interview. The CIS collects demographic information including age, ethnicity, and education as part of standard procedure; therefore, this information is not collected at any of the follow-up interviews.

Key outcome measures specified in the original grant submission are: 1) intention to undergo risk assessment/genetic testing; 2) sense of preparation to undergo risk assessment/genetic testing; 3) satisfaction with the information provided by the interventions; and 4) degree of knowledge regarding: familial risk, environmental risk factors, procedures for conducting risk assessment/ genetic testing, advantages and disadvantages associated with risk assessment/genetic testing, methods for reducing risk, and available risk assessment programs. In addition, drawing from the C-SHIP model, several additional measures are included in the assessment tool as indicators of process or mediating variables (i.e., variables that may explain how the intervention influences outcome measures). These include measures of: 1) risk perceptions, 2) beliefs and expectancies, 3) affect, 4) self-regulatory behaviors, and 5) monitoring-blunting.

Risk perceptions are assessed using 4 items (e.g., "In your opinion, compared to other women your own age, what are your chances of getting breast cancer?" "In your opinion, compared to other women your own age who have a close relative with breast cancer, what are your chances of getting breast cancer?) Initially the questions are stated regarding breast cancer and are then repeated referring to ovarian cancer. Items are scored using a five point Likert scale ranging from much lower than average to much higher than average.

Cancer specific worry is being measured using the scale created by Lerman and colleagues (Lerman, et.al., 1994).

Disadvantages/Advantages to pursuing risk assessment are assessed using 4 items (e.g., To what degree would you agree with the following statements: "Risk assessment/genetic testing can help you better understand your risk for breast/ovarian cancer, so that you can make decisions about pursuing risk reduction approaches, such as surgery and/or medications." "Risk assessment/genetic testing can help you better understand your risk for breast/ovarian cancer, so that you can determine if you need to increase screening, such as mammography or transvaginal ultrasounds." "Risk assessment/genetic testing can jeopardize your insurance coverage." "Risk assessment/genetic testing can have a negative emotional impact on you and on your family." Responses are coded using a four point scale ranging from strongly disagree to strongly agree.

Knowledge concerning issues surrounding risk assessment/genetic testing for breast cancer, inheritable cancer, and breast cancer prevention is being assessed with a revised version of the Breast Cancer Heredity Knowledge Scale (BCHK) which measures knowledge about breast cancer incidence and prognosis, risk factors, screening, disease presentation and treatment, and Heritable Breast Cancer (Ondrusek et al., 1999). This scale lists concepts covered in the

enhanced intervention (e.g., the benefits and limitations of screening). Items are worded in a true/false format.

Intentions to pursue and preparedness to seek risk assessment/genetic counseling will be assessed using the following three items: "At this point, how would you rate your knowledge about breast and ovarian cancer risks and the process involved in undergoing risk assessment/genetic testing for breast and ovarian cancer?" "How would you describe your present behavior with regard to risk assessment and genetic testing for breast and ovarian cancer?" "If you decided to pursue risk assessment/genetic testing, how prepared would you be to undergo these procedures?"

Performance of screening behavior is being measured using the following questions: "How often do you perform Breast Self Exam?" "How often do you go for mammograms?" "In the past six months: how many transvaginal ultrasounds have you had? How many pelvic exams have you had? How many CA 125 blood test have you had?"

Satisfaction with the CIS will be assessed using 5 items (e.g., "How satisfied do you feel with the information you received from the Cancer Information Service?" "To what extent would you recommend that others contact the Cancer Information Service for this type of information?").

Attentional style, a key component that evaluates key constructs within the C-SHIP model, will be assessed with the Monitoring-Blunting Style Scale (MBSS). This scale measures patients' responses to four structured stress-evoking scenarios that the participant is asked to vividly imagine. Reliability, discriminative validity, and utility of this measure are well established in the oncologic context (Miller & Diefenbach, 1998).

Actual risk is being measured using the Gail Model (Spiegelman, et.al., 1994).

Development of CATI System

How best to implement, manage and coordinate the study was a subject of great import and interest for both the Behavioral and Psychosocial Medicine Program at FCCC and the CIS. The study requires close coordination and constant monitoring to ensure data integrity and timely follow-up. In addition, assuring a constant flow of communication between the two programs demanded a shared system that could accommodate initial interventions and three series of follow-up interviews. Making use of current technology and the expertise available at Fox Chase was a solution to the coordination and implementation question. Project staff decided to develop a Computer Assisted Telephone Interview, or CATI, system.

Ideally, the CATI system provides real-time data entry and automatically records study information in a confidential database. The information remains on file generating custom reports and permitting future analyses. The CATI can also ensure that researchers adhere to protocol as it has built-in skip patterns and can support multiple survey designs for the same project. We requested a CATI system that would begin with the Informed Consent. Contact information for those women who agree to participate (i.e., names, addresses, and telephone numbers) is entered into the database, which automatically randomizes women to the enhanced or standard intervention. Information Specialists conduct the interventions on-line. Once the

data is completely entered, the system is able to generate custom letters including information on family cancer patterns for women in the enhanced group. It also generates a standard thank-you letter for participants in both groups. The system tracks the due dates for the follow-up interviews. A few days before the woman is due for a follow-up call her name appears in the system. If she again agrees to consent, the appropriate follow-up (2-week, 2-month, or 6-month) is generated. For those women who are unable to complete a call, the system allows for a "break-off" or, temporary holding database, that enables us to maintain what data has already been collected and gives us what information we need to contact the woman to complete the call.

The system allows for different degrees of access. For instance, Information Specialists may only access the initial interview (which contains the Informed Consent). Researchers conducting follow-up interviews have access to those interviews as well as study data. Degrees of access are decided by project staff based on levels of responsibility and need.

Project staff met with FCCC programmers in August 1999 to discuss the design and feasibility of developing a CATI system for the study. The projected start date for the study was the middle of September. (We actually began recruiting women to the study in October.) While it was understood that the program would not be ready for implementation that soon, we hoped to have the initial interview functional by October. In fact, due to a number of obstacles, we did not have a functional system until January 2000. The programming was far too complicated to complete in just a few months. Also, there was a difference in the understanding of what was being requested, resulting in aspects of the application that did not suit the needs or expectations of the researchers and creating more work for the programmers. An unforeseen problem was the inability of an institutional server on which the application rests to support multiple users at the same time. That problem did not become apparent until the system was tested by an influx of calls in March 2000. Although no data was lost, Information Specialists had to revert to conducting the interventions on paper until the problem was first identified and then resolved. The server problem was addressed by upgrading the operating software. Programmatic problems are addressed as they arise.

A CATI system requires a great deal of planning, development and sophisticated programming. Because the interviews are so interconnected, small changes to one section can require major changes in coding throughout. Inserting or deleting sections not only makes additional programming demands, it also necessitates changes in screen configuration. There may be challenges for the non-technical person in articulating needs and desires to the programmer. For the programmer, too, there may be disconnects between what the researcher is requesting and how that request is interpreted from a programming perspective. The development of a CATI system requires months of planning and preparation. For researchers who plan to use this technology to conduct their research, it is imperative to factor in sufficient time for development as well as usability testing. A CATI system also requires a network that can support it. The CIS computers were unable to run the application without error until they had more memory and an upgrade to a more stable network-operating platform (Windows NT). We have been fortunate to have in-house programmers and support from our institution. Their assistance and accessibility have been invaluable.

Implementation of the Study

In October 1999, we gained final IRB approval from Fox Chase Cancer Center for the randomized trial phase of this study and began recruiting women. As discussed above, Information Specialists conducted the initial interviews over the telephone, recording the answers on paper. For ease of use and quality assurance, forms were color-coded. The Informed Consent included space to collect subjects' names, addresses and phone numbers as well as directions for randomization. Completed interviews were given to the study coordinator who kept all original interviews in a locked file and forwarded copies to the researcher conducting follow-up interviews. All data collected on paper were entered into the database when it was completed. Because the automated system for tracking due dates was not ready until Spring 2000, all follow-ups were coordinated between the CIS study coordinator and the research assistant conducting the follow-up interviews. Follow-up interviews were also recorded on paper until the system could accommodate both data entry as well as live reporting.

Women calling the CIS with questions about their personal risk for inherited disease, risk assessment services and/or genetic testing are asked to consent. Of all eligible women calling the CIS, 78% have agreed to participate. CIS supervisors help ensure adherence to protocol through regular call monitoring. Reviewing CIS call record forms allows us to see that all eligible women are being asked to participate. To date, less than 10% of all potentially eligible women have not been recruited for the project.

Outreach/Promotion

Outreach and promotional activities for this study was primarily through print media. In the Fall of 1999, an article appeared in The HUB, the newsletter of the Atlantic Region Cancer Information Service Partnership Program. This publication is mailed to 2,150 partners/organizations in cancer control.

In April 2000, promotion of the project was conducted using a different print media. An "Ask the CIS" newspaper column was the medium for this effort and was sent to 20 local papers in Delaware, 132 local papers in New Jersey and 166 papers in Pennsylvania. Later during the month of April, we sent a letter to health professionals along with fliers and brochures to 492 PA partners, 145 New Jersey partners and 54 Delaware partners. All these partners have a particular focus on breast cancer.

On the first of May 2000, 1,527 packets containing an introduction letter, flier and brochure were mailed to OB/GYN physicians in the PA, DE and NJ region. Partnership staff also held discussions with the American Cancer Society about developing a similar article for their newsletter

In June, there were four responses to the physician-targeted mailing requesting large numbers of additional fliers and brochures so that they may be placed in doctors' offices and patient waiting areas indicating that the promotional materials were well received by this group.

The last promotion to date occurred in June during the FCCC Network Program Managers Meeting, where CIS staff provided an overview and update of the project along with letters, fliers and brochures for distribution at their own institutions.

An unanticipated source of promotion has been the Study of Tamoxifen and Raloxofene (STAR) trial. This national breast cancer prevention trial is targeting women at high risk for the disease. Many of the women calling the CIS for information about and referrals to participating STAR sites are also eligible for this study. We hope to work more with local STAR coordinators to promote both studies in the tri-state region.

Summary of the Implementation

At the time of submission of this report we have randomized 82 women to either the standard or enhanced treatment condition and, thus, have completed 82 baseline interviews. In addition, we have completed 60 two-week follow-up assessments, 48 two-month follow-up assessments, and 5 six-month follow-up assessments. For this Annual Report, our analyses focused on accomplishing three specific aims as outlined below.

> **[Aim 1] Overall Description at Baseline.** To describe the overall sample of participants in terms of: 1) background variables (i.e., demographic variables, reason for calling the CIS, medical status, and past utilization of risk assessment services), 2) screening variables (e.g., mammography, readiness to pursue risk assessment and genetic testing), 3) knowledge concerning breast/ovarian cancer risk factor (e.g., age), 4) perceived breast/ovarian cancer risk, 5) emotional distress related to perceived breast/ovarian cancer risk, 6) overall and specific knowledge concerning breast/ovarian cancer risk assessment and genetic testing procedures, and 7) immediate responses to the intervention (i.e., satisfaction with information received, likelihood of referring others to the CIS. These analyses will allow for the preliminary assessment of the external validity of the present study.
>
> **[Aim 2] Participant Attrition.** To examine rates of, and reasons for, participant attrition in order to verify our ability to retain participants in the study, assess whether there is differential attrition across study conditions, and substantiate our ability to meet our recruitment goals.
>
> **[Aim 3] Randomization.** To examine any and all potential differences between enhanced intervention participants and standard intervention participants in order to verify that the

randomization scheme was successful in distributing any possible confounding or extraneous variables evenly across the two study conditions. Specifically, we assessed potential differences between treatment conditions in terms of the 7 types of variables listed in Aim 1.

[Aim 4] Knowledge Levels. To highlight baseline levels of knowledge concerning breast/ovarian cancer risk assessment and genetic testing, and breast/ovarian cancer etiology and prevention. This analysis was intended to offer to the Review Committee further data from our population supporting the need for the development and refinement of an enhanced intervention that would prepare women as they pursue information and services for breast/ovarian cancer risk assessment and genetic testing.

Summary of Baseline Data

The results of our analyses to address each aim described above are delineated below in the respective sections. The Statistical Package for the Social Sciences (SPSS) was used for the statistical analyses. The specific procedures used to address the respective aim are described within the respective sections. All the analyses performed utilized baseline data only, since an insufficient number of participants have been interviewed at follow-up to allow for meaningful assessment of follow-up data.

Overall Sample Description at Baseline: For ease of presentation and evaluation, the results are presented in tabular format (see Tables 1-8). Means and standard deviations were calculated for interval or ratio scale variables and frequency distributions were computed for nominal or ordinal scale variables. Since our data is collected through a web-based program and require technical transformation for data analysis, we present sample description for data collected 2 weeks prior to the submission of this report. This explains why the sample description section to follow is based on a sample size of 74 participants, while we indicate above that we have recruited 82 women into the study at the time of the submission of this report.

Table 1. Overall Description of the Entire Sample (N = 74).*

Background Variables		
Variable	**Frequency or Mean**	**Percentage or Standard Deviation**
Age	44.8 years	12.13 years
Education	8.62 years	19.38 years
Race/Ethnicity		
African American	1	1.4%
Caucasian	62	83.8%
Other	2	2.7%
Reason for Calling CIS		
For breast cancer risk information	55	74.3%
For ovarian cancer risk information	13	17.6%
For both breast and ovarian cancer risk information	4	5.4%
Cancer Diagnosis		
Yes	11	14.9%
No	63	85.1%
Past Use of Risk Assessment Services		
Yes	8	10.8%
No	65	87.8%

Table 2. Preventive Behaviors

Screening Variables		
Variable	**Frequency or Mean**	**Percentage or Standard Deviation**
Mammography		
Once every few months	1	1.4%
A couple time per year	6	8.1%
Once a year	39	52.7%
Once every few years	8	10.8%
Almost never	1	1.4%
Never	10	13.5%
Breast Self-Exam		
More than once per week	5	6.8%
At least once per week	8	10.8%
A couple times per month	10	13.5%
At least once per month	25	33.8%
A few times per year	6	8.1%
At least once per year	3	4.1%
Almost never	3	4.1%
Never	4	5.4%
Pelvic Exam		
Yes	8	10.8%
No	66	89.2%
Transvaginal Ultrasound		
Yes	2	2.7%
No	72	97.3%
CA125		
Yes	3	4.1%
No	71	95.9%
Readiness to Pursue Risk Assessment/Genetic Testing		
Precontemplation	13	17.6%
Contemplation	39	52.7%
Preparation	18	24%
Action	2	2.7%
Preparedness to Pursue Risk Assessment/Genetic Testing		
Not at all	9	12.2%
Somewhat	36	48.6%
Quite	11	14.9%
Very	14	18.9%

Table 3. Perceived Risk Factors

Callers' Cancer Risk Concerns (What things do you think contribute to your risk for breast/ovarian cancer?)		
Variable	**Frequency or Mean**	**Percentage or Standard Deviation**
Age Yes	7	9.5%
Early Menarche Yes	6	8.1%
Late Menopause Yes	2	2.7%
Family History/Genetics Yes	59	79.7%
Personal History of Cancer Yes	16	21.6%
Pregnancy Yes	10	13.5%
Previous Breast Biopsies Yes	8	10.8%
Lifestyle Yes	22	29.7%
Diet Yes	14	18.9%
Smoking Yes	12	16.2%
Exercise Yes	3	4.1%
Alcohol Yes	2	2.7%
Stress Yes	1	1.4%
Personal Health History Yes	9	12.2%
Hormone Replacement Therapy Yes	8	10.8%
DES Yes	0	0%
Abortion Yes	0	0%
Oral Contraceptives Yes	1	1.4%
Environment Yes	3	4.1%

Table 4. Perceived Risk

Perceived Breast/Ovarian Cancer Risk		
Variable	**Frequency or Mean**	**Percentage or Standard Deviation**
Breast cancer risk vs. other women the same age		
Very low	3	4.1%
Somewhat low	7	9.5%
Average	11	14.9%
Somewhat high	29	39.2%
Very high	20	27.0%
Ovarian cancer risk vs. other women the same age		
Very low	7	9.5%
Somewhat low	16	21.6%
Average	14	18.9%
Somewhat high	1	16.2%
Very high	6	8.1%
Breast cancer risk vs. other women the same age with family history		
Very low	4	5.4%
Somewhat low	11	14.9%
Average	12	16.2%
Somewhat high	25	33.8%
Very high	17	23.0%
Ovarian cancer risk vs. other women the same age with family history		
Very low	12	16.2%
Somewhat low	13	17.6%
Average	17	23.0%
Somewhat high	12	16.2%
Very high	4	5.4%

Table 5. Anxiety/Distress re: Cancer Risk

Emotional Distress Concerning Cancer Risk		
Variable	**Frequency or Mean**	**Percentage or Standard Deviation**
Have thoughts about getting breast cancer		
Not at all	14	18.9%
Sometimes	25	33.8%
Often	20	27.0%
A lot	13	17.6%
Have thoughts about getting ovarian cancer		
Not at all	41	55.4%
Sometimes	18	24.3%
Often	6	8.1%
A lot	6	8.1%
Thoughts about breast cancer risk affect mood		
Not at all	39	52.7%
Sometimes	19	25.7%
Often	6	8.1%
A lot	8	10.8%
Thoughts about ovarian cancer risk affect mood		
Not at all	51	68.9%
Sometimes	14	18.9%
Often	5	6.8%
A lot	2	2.7%
Thoughts about breast cancer risk affect daily activities		
Not at all	61	82.4%
Sometimes	10	13.5%
Often	0	0%
A lot	2	2.7%
Thoughts about ovarian cancer risk affect daily activities		
Not at all	67	90.5%
Sometimes	6	8.1%
Often	0	0%
A lot	0	0%

Table 6. Knowledge Variables

Knowledge Variables		
Rating of overall knowledge about risks and assessment		
Not at all knowledgeable	8	10.8%
Not very knowledgeable	25	33.8%
Somewhat knowledgeable	34	45.9%
Very knowledgeable	7	9.5%
Many women who do not have any of the known risk factors still get breast cancer		
Correct	65	87.8%
Incorrect	9	12.2%
Over a lifetime, 1 out of 9 women will develop breast cancer		
Correct	62	83.8%
Incorrect	12	16.2%
Women who are over 50 years of age are more likely to get breast cancer than are younger women		
Correct	55	74.3%
Incorrect	19	25.7%
A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer		
Correct	52	70.3%
Incorrect	22	29.7%
Early detection means a greater chance of surviving breast cancer		
Correct	72	97.3%
Incorrect	2	2.7%
Women over age 40 should have mammograms at least every two years		
Correct	55	74.3%
Incorrect	19	25.7%
A woman whose mother was diagnosed with breast cancer at age 69 is considered to be at high familial risk for breast cancer		
Correct	24	32.4%
Incorrect	50	67.6%
A woman can inherit breast cancer gene mutations from her father		
Correct	43	58.1%
Incorrect	31	41.9%

Table 7. Knowledge Variables

Knowledge Variables (Continued)		
Most women who develop breast cancer do not have a family history of the disease		
Correct	42	56.8%
Incorrect	32	43.2%
Ovarian cancer and breast cancer in the same family can be a sign of hereditary breast cancer		
Correct	62	16.2%
Incorrect	12	83.8%
Testing for breast cancer gene mutations can tell a woman if she has breast cancer		
Correct	49	66.2%
Incorrect	25	33.8%
Men cannot inherit breast cancer gene mutations		
Correct	66	89.2%
Incorrect	8	10.8%
If there are other types of cancer in my family, I may have a higher than average risk of developing breast or ovarian cancer		
Correct	51	68.9%
Incorrect	23	31.1%
The process of risk assessment and genetic testing is simple, involving only a physical exam and blood test.		
Correct	9	12.2%
Incorrect	65	87.8%
One of the advantages of risk assessment and genetic testing is that, finding out your risk, can help you make decisions about pursuing risk reduction options, such as surgery and medications.		
Correct	71	95.9%
Incorrect	3	4.1%
There are no real disadvantages to pursuing risk assessment and genetic testing		
Correct	46	37.8%
Incorrect	28	62.2%
A woman who develops breast cancer at an early age is more likely to have inherited breast cancer		
Correct	35	47.3%
Incorrect	39	52.7%
Knowledge Total Score (Out of 17)	11.61	2.83

Table 8. CIS

Responses to the CIS		
Level of satisfaction with information received		
Not at all	0	0%
A little	2	2.7%
Moderately	3	4.1%
Quite a bit	16	21.6%
Very much	42	56.8%
Degree to which they will recommend the CIS to others		
Definitely no	0	0%
Probably not	0	0%
Maybe	0	0%
Probably yes	51	68.9%
Definitely yes	11	14.9%

Note. * indicates that frequencies do not always total 74, since participants may have omitted answering particular questions.

Differences Between Study Conditions: In order to assess for the presence of any potential extraneous or confounding variable, we examined differences between the study conditions in terms of baseline measures described in Aim 1. For ordinal, interval, or ratio data (e.g., age, rate of mammography, perceived risk, emotional distress, level of satisfaction) the ANOVA procedure was used, with the two intervention groups serving as the levels of the independent variable. For nominal data (e.g., ethnicity, perceived risk factors, knowledge items), the chi-square procedure was utilized.

With regard to all background variables (i.e., demographic variables, reason for calling, cancer history, past use of risk assessment services), there were no significant differences between the study conditions (i.e., all p's > .05). Likewise, there were no significant differences between study conditions with regard to baseline measures of: 1) breast and ovarian cancer screening, readiness to pursue risk assessment and genetic testing, and degree to which participants felt prepared to pursue risk assessment and genetic testing; 2) level of endorsement of the CIS (i.e., satisfied with information received, recommend CIS to others), 3) degree of perceived risk of developing breast or ovarian cancer, 4) level of emotional distress concerning developing breast or ovarian cancer, and 5) participant's total level of knowledge about breast and ovarian cancer and about risk assessment procedures (i.e., all p's > .05).

There were also no significant differences between enhanced and control participants with regard to the endorsement of specific breast and ovarian cancer risk factors (i.e., all p's > .05). Finally, baseline levels of correct responses to the true or false assessment of knowledge about breast and ovarian cancer risk assessment and genetic testing and etiology were contrasted across the two study conditions. Of the 17 questions assessed, the two study conditions differed statistically on two. In particular, a greater proportion of enhanced participants (71%) responded correctly to

the question concerning *"A woman can inherit breast cancer gene mutations from her father"* ($\square^2$ [1] = 4.92, p < .05), compared to standard participants (46%). Similarly, while 74% of enhanced participants responded correctly to the question *"There are no real disadvantages to pursuing risk assessment and genetic testing"*, 51% of participants in the standard conditions responded correctly to this question ($\square^2$ [1] = 4.22, p < .05). We expect that, with the collection of additional data, these baseline differences will no longer be evident. If, however, they remain after the collection of additional data, these questions will either be omitted from the final analyses or the baseline levels of knowledge will be controlled for by treating these baseline measures as covariates in subsequent analyses.

Participant Attrition - Rates and Reasons

To date we have recruited 82 participants. We have completed 60 two-week follow-ups; eight two-week follow-ups are in the process of being completed, 10 were missed because we could not reach the participant, and 4 women dropped out of the study at this point. We have completed 48 two-month follow-ups; 17 two-month assessments are in the process of being completed, 10 were missed because we could not reach the participant, and 3 women withdrew from the study at this point. Finally, 5 six-month follow-ups have been completed, with the majority of participants not due for their six-month assessment. Two women dropped out of the study at the 6-month assessment point. If women do not complete one follow-up assessment, we still try to complete subsequent follow-up assessments.

Therefore, we have had a total of 9 women withdraw from the study – an attrition rate of 11%. Five of the women who withdrew from the study were randomized to the enhanced condition, with the remaining 4 women who withdrew from the study receiving the standard treatment. Reasons given for withdrawing from the study were: a) not interested (2 women), b) personal health reasons (2 women), c) believing that there was nothing to gain from participation (1 woman), d) family health problems (2 women), e) not wanting to think about cancer risk (1 woman), and f) a disconnected phone (1 woman). Overall, these data indicate that we are: 1) retaining participants in the study sufficiently to meet our recruitment goals, and 2) there is no differential attrition across study conditions.

Levels of Knowledge About Risk Assessment Procedures and Breast/Ovarian Cancer Etiology and Prevention

As a rationale for implementing this study, we highlight findings that indicate that women interested in pursuing breast/ovarian cancer risk assessment and genetic testing are unprepared and lack important knowledge about this issue to make informed decisions. We underscore this analysis in order to provide additional evidence-based support for the overall rationale supporting the initiation of this study.

Indeed, as shown in Table 1, close to 60% of women indicated that they are inadequately prepared to pursue risk assessment and genetic testing. In addition, women were found to be lacking important information that would enable them to make informed decisions about pursuing risk assessment and genetic testing. When women were asked to rate their degree of knowledge concerning breast and ovarian cancer risks and the process of risk assessment and

genetic testing, close to 50% of them indicated that they have inadequate knowledge. Further, on the 17-item knowledge survey, the average of correct responses was 11.63 (SD = 2.83). Examination of the specific questions revealed that a high proportion of women were responding incorrectly to questions concerning: 1) the relationship between age at diagnosis of cancer and risk for inherited breast or ovarian cancer; 2) the potential for fathers to pass along genetic mutations linked to breast and ovarian cancer risk; 3) the link between ovarian and breast cancer risk; 4) the complexity of risk assessment and genetic testing procedures; and 5) the possible disadvantages of risk assessment and genetic testing. Each of these areas of knowledge are targeted by the enhanced intervention. Thus, we expect to see improved knowledge among enhanced participants at follow-up assessments, compared to participants receiving the standard intervention.

Key Research Accomplishments

- A broad, comprehensive training for Information Specialists was developed, implemented and evaluated:
  - Specialists improved most in identifying inherited cancer patterns.
  - After training, Specialists felt more comfortable and capable in delivering complex, genetic risk information.
  - Quality assurance activities confirm that Specialists demonstrate greater skill and confidence in relaying this information to study participants.

- A modified training curriculum has been created to focus specifically on the content areas addressed in the intervention and on the skills necessary to conduct the intervention.

- After meeting with expert advisors, the informed consent and interventions were finalized and implemented (October 1999).

- A Computer Assisted Telephone Interview (CATI) system was developed to facilitate baseline data collection, follow-up and analysis:
  - Women who consent to the study are automatically randomized to receive the standard or enhanced intervention.
  - Specialists complete the baseline interviews on-line.
  - Personal thank-you letters are generated at the completion of a call.
  - Follow-up interviews appear in the database 2 days before their due dates and remain there until they are completed or terminated.
  - Follow-up interviews are also completed on-line.
  - The system can recover calls that were never completed because of performance problems as well as maintain incomplete participant data until an interview can be finished.
  - Researchers have access to all study data.

- We have completed 82 baseline interviews, 60 two-week interviews, 48 two-month interviews and 5 six-month interviews.

- Preliminary analysis of data supports the rationale for this study:
  - Close to 60% of women report they are inadequately prepared to pursue risk assessment services.
  - Almost 50% indicate they have insufficient knowledge about cancer risk factors and the process of risk assessment.
  - The average number of correct responses on the 17-item knowledge scale was only 11.63 (SD = 2.83).

- Randomization has been successful, attrition rates are acceptable and Specialists are conducting the interventions as intended.

Reportable Outcomes

Miller, S.M., Buzaglo, J.S., Simms, S., Green, V.A., Bales, C., Mangan, C.E., & Sedlacek, T.V. (1999). Monitoring styles in women at risk for cervical cancer: Implications for the framing of health-relevant messages. In Special Issue "Innovative Approaches to Health Behavior Change," Annals of Behavioral Medicine, 21, 91-99.

Miller, S.M. Fang, C.Y., Manne, S.L., Engstrom, P.E., & Daly, M.B. (1999). Decision making about prophylactic oophorectomy among at-risk women: Psychological influences and implications. Gynecologic Oncology, 75, 406-412.

Diefenbach, M., Miller, S.M., & Daly, M. (1999). Specific worry about breast cancer predicts mammography use in women at risk for breast and ovarian cancer. Health Psychology, 18, 532-536.

Savard, J., Miller, S.M., Mills, M., O□Leary, A., Douglas, S., Mangan, C.E., Belch, R., & Winokur, A. (1999). The influence of sleep quality and depression on immunocompetence in low-income women at risk for cervical cancer. Psychosomatic Medicine, 61, 496-507.

Diefenbach, M.A., Schnoll, R.A., Miller, S.M., & Brower, L. (2000). Predictors of interest in genetic testing for prostate cancer risk. Cancer Practice, 8, 1-5.

Miller, S.M. & Schnoll, R.A. (2000). When seeing is feeling: A cognitive-emotional approach to coping with health stress. In M. Lewis & J. Haviland (Eds.), Handbook of emotion. NY: Plenum Press.

Schnoll, R.A., & Miller, S.M. (2000). Hospital based smoking cessation efforts for cancer patients Primary Care and Cancer, 20, 10-15.

Diefenbach, M.A., Green, V.G., Gray, T., Patterson, F., & Miller, S.M. (2000). Targeted smoking cessation interventions for special populations. Primary Care and Cancer, 20, 52-56.

Roussi, P., Miller, S.M., & Shoda, Y. (2000). Discriminative facility in the face of threat: Relationship to psychological distress. Psychology and Health, 15, 21-33.

Miller, S.M., Fang, C.Y., Diefenbach, M.A., & Bales, C. (in press). Tailoring psychosocial interventions to the individual□s health information processing style: The influence of monitoring versus blunting in cancer risk and disease. In A. Baum & B. Andersen (Eds.), Psychosocial interventions and cancer. Washington D.C.: American Psychological Association.

Miller, S.M., Schnoll, R.A., & Knowles, J. (in press). Psychosocial aspects of cancer in the elderly: You're as healthy as you feel. In K. W. Schaie, S. Willis, & H. Leventhal (Eds.), Societal structures and effective healthy behavior in the elderly. Annual Review of Gerontology and Geriatrics. Volume 19. New York, NY: Springer Publishing.

Fleisher, L., Miller, S., Schnoll, R., McKeown-Conn, N., Brower, L. "Developing a telephone intervention to assist women in understanding inherited breast/ovarian cancer risk." Presented at the 24th Annual Meeting of the American Society of Preventive Oncology , Bethesda, MD, March 5-7, 2000.

Fleisher, L., Miller, S., Schnoll, R., McKeown-Conn, N., Brower, L. "Development of an Intervention to Increase Women's Knowledge of Cancer Risk and Risk Programs." Presented at the DoD Breast Cancer Research Program Era of Hope Meeting, Atlanta, GA, June 8-12, 2000.

Miller, S.M. The Cancer Information Service Post-Award Meeting. Invited participant and speaker on: The Cancer Information Service as a model for research. Washington, DC, March 2000.

Computer Assisted Telephone Interview (CATI) system.

Conclusions

At almost 50% accrual, preliminary data corroborate current literature suggesting that women lack knowledge about and are unprepared for the process of cancer risk assessment and genetic testing. In addition, the data supports the rationale and need for this study and others like it. The majority of women who have agreed to participate in this pilot have indicated that they would not feel adequately prepared to pursue risk assessment services. Moreover, almost half of them report that they have insufficient knowledge regarding breast and ovarian cancer risks and the process of formal risk assessment. This self-reported lack of knowledge is substantiated by a large proportion of incorrect responses to questions about age as a risk factor, inheriting breast cancer gene mutations from one's father, and the links between breast and ovarian cancers, among others. We expect to see an increase in knowledge and a greater sense of preparedness among those in the enhanced group at follow-up. Nevertheless, baseline data confirm the need for more and better information about breast/ovarian cancer risks, risk assessment and genetic testing.

The creation of the CATI system was such a complicated, time-consuming process, that if we had to do it over, we would allow for much more time for development, testing and refining. As it is, the system is functioning at an acceptable level. However, initial problems with performance and usability were such that Specialists and researchers alike were hesitant to trust in its ability to perform as intended. Having support from and access to the programmers, however, enabled us to address problems in a timely manner. They were quick to respond to requests for modifications to the intervention. They were also available whenever a programming or performance problem arose. This close collaboration was imperative to the success of the CATI system. Despite the initial problems, the CATI system has allowed us to work more efficiently with fewer man-hours. Again, allowing for more time to design and develop the system would assure better usability and function when the study is implemented.

Staff training for this study began before the intervention was completely developed and extended over a 4-month period. We knew there would be core content areas included in whatever intervention would be developed. Any content that would even potentially be part of

the intervention also needed to be addressed in training. This extensive training, therefore, included more information than is covered in the final intervention. Staff, however, was well prepared when it came time to implement the study. They now had a solid foundation in cancer genetics and risk assessment and they felt comfortable relaying this information to callers. This comprehensive training was successful in preparing staff for the project, but it was not feasible for new staff coming into the CIS. A revised curriculum, covering the same topics in less detail, was created. This new training meets the demands of the intervention sufficiently and integrates well with other components of initial CIS training.

Finally, original estimates of our ability to recruit 200 women to the study within the proposed timeline (months 12-28) were based on calls coming into the CIS shortly after the discovery of the BRCA 1 & 2 genes. Since that time, calls about genetic risk for breast/ovarian cancer have leveled off. To boost recruitment, we will need to concentrate on greater promotion of the study within the Atlantic Region.

References

Spiegelman D, Colditz GA, Hunter D, Hertzmark E. (1994). Validation of the Gail et al model for predicting individual breast cancer risk. J Natl Cancer Inst. **86**:600-607.

Iglehart, J. D., A. Miron, et al. (1998). "Over estimation of hereditary breast cancer risk." Ann Surg **228**(3): 375-84.

Lerman C, Daly M, Masny A, Balshem A (1994). "Attitudes about genetic testing for breast-ovarian cancer susceptibility." J Clin Oncol, **12**(4): 843-850.

Miller, S.M., Shoda, Y, & Hurley, K. (1996). Applying cognitive –social theory to health protective behavior: Breast self-examination in cancer screnning. Psychological Bulletin, **119**, 70-94.

Miller, S.M., & Diefenbach, M.A. (1998). The Cognitive-Social Health Information-Processing (C-SHIP) model: A theoretical framework for research in behavioral oncology. In D.S. Krantz & A. Baum (Eds.), Technology and Methods in Behavioral Medicine (pp. 219-244). Mahwah, NJ: Lawrence Erlbaum.

Ondrusek, N., Warner, E., & Goel, V. (1999). Development of a knowledge scale about breast cancer and hereditary (BCHK). Breast Cancer Research and Treatment, **53**, 69-75.

Appendices

Appendix 1

Project Advisory Committee Members (Attending)

Marilyn Arnott, Ph.D.	*Living Beyond Breast Cancer*
Carol Blickley	*Family Risk Assessment Program*
Barbara DeLuca	*Linda Creed Breast Cancer Foundation*
Paul Engstrom, M.D.	*Fox Chase Cancer Center*
Caryn Lerman, Ph.D.	*Georgetown University*
Novella Lyons	*Women of Faith and Hope*
Agnes Masny, R.N., M.P.H., M.S.N.	*Fox Chase Cancer Center*
Judi Much, R.N., M.S.N.	*Cancer Institute of New Jersey*
Joan Pouch	*Family Risk Assessment Program*
Linda Slan, M.S.	*Cancer Information Service Branch/NCI*
Laura Toole, M.S.	*Northeast Regional Cancer Center*

Project Advisory Committee Members (Unable to Attend)

Generosa Grana, M.D.	*Cooper Medical Center*
Pamela Sankar, Ph.D.	*Center for Bioethics, U. of P.*
Jill Stopfer, M.S.	*University of Pennsylvania*

Project Staff

Suzanne M. Miller, Ph.D.	*Director, Psychosocial and Behavioral Medicine*
Linda Fleisher, M.P.H.	*Project Director, Cancer Information Service*
Robert Schnoll, Ph.D.	*Research Associate*
Lisa Brower, B.A.	*Research Assistant*
Kim Le Maitre, B.S.	*Training Coordinator, CIS*
Nancy McKeown-Conn, B.A.	*Research Coordinator, CIS*
Cherie Riggs, M.A.	*Assistant Project Director, CIS*

Appendix 2

ECRF# _____
Staff ID _____

Determine Eligibility

Is caller... ☐ Female >18 y.o. calling about breast/ovarian cancer risk (1)
☐ Female >18 y.o. calling about risk assessment/genetic counseling (1)
☐ Other female (2)

☐ (1) If Eligible continue with informed consent, randomization and intervention, complete ECRF at end of intervention
☐ (2) Ineligible— go to demographics proceed with usual service & complete CIS Electronic Call Record Form

Informed Consent

Thank you for calling today. The Cancer Information Service can provide you with information and free materials about understanding your risk for cancer. I can share information over the phone, as well as send you materials that you might find helpful. You may also be interested in participating in a special research study we are conducting in collaboration with Fox Chase Cancer Center.

Information Specialist will explain to caller that he/she will now read some information. It might be a little lengthy but it is very important. (e.g., ***I'd like to tell you a little bit about it and explain what would be involved if you decided to participate.)***

We are working to improve our services and to tailor our information to women calling with concerns about breast/ovarian cancer. To do so, we are currently evaluating two different approaches to providing information about cancer risk, risk assessment and genetic testing. Participation in this study is completely voluntary and all your answers will be confidential. Only the researchers will have access to the information you provide, which will be stored in a secure computer file. We will certainly provide appropriate information and materials should you decide not to participate. Participation would require two things on your part: First, you would agree to be randomly chosen for one of two ways of providing the information you called for. This will involve answering some questions that will help us evaluate the two approaches and will take about 15-20 minutes. Second, you would agree to participate in three 15-minute follow-up telephone interviews that would help us compare the effectiveness of these two approaches and get your reactions to the materials. These interviews would occur in two weeks, two months and then six months from now. You may refuse to answer any questions and can withdraw at any time. There is little risk involved in answering these questions and what we learn from your responses will help our service improve the way we deliver information about cancer risk, risk assessment and genetic testing services. Are you willing to participate?

☐ (1) **YES**, agree
☐ (2) **NO**, do not agree— **Complete CIS Electronic Call Record Form,**

demographic information and then go to standard counseling

Before we get started with the information that you are requesting, we need to get your name, address and telephone number so we can send you materials and call you in a few weeks. Please be assured that all information provided by you will be kept strictly confidential.

Contact Information

First name _____ **Age** _____

Last name _____

Address_____

City _____ State _____ Zip Code _____

County _____

Phone Number ( ) _____ - _____

When is the best time to reach you?

☐ Morning ☐ Afternoon ☐ Early Evening

Is there another number where we can reach you?

(_____) _____ - _____

☐ Relative ☐ Work ☐ Other

May we identify ourselves as calling from FCCC when we call back?

☐ Yes ☐ No

Randomization: Use last number of phone number to randomize

☐ Standard Counseling (Odd Numbers: 1,3,5,7,9)

☐ Enhanced Counseling (Even Numbers: 0,2,4,6,8)

10/7/99

Appendix 3

ECRF # _____

Staff ID _____

Date _____
STANDARD INTERVENTION

Start Time _____
(Follows informed consent document)

Caller is asking about: ☐ Breast Cancer ☐ Ovarian Cancer ☐ Both

Let me begin by asking just a few short questions:

1) Have you ever been diagnosed with cancer? ☐ YES ☐ NO ☐ Don't Know ☐ Refused

If yes - What kind of cancer were you diagnosed with? ***Age (at diagnosis)?*** _____

If no, continue with question 2.

2) Have you ever pursued risk assessment services? ☐ YES ☐ NO

If yes – When?

If no, continue with question 3.

Please read all responses for the following questions. (Questions read verbatim)

3) At this point, how would you rate your knowledge about breast and ovarian cancer risks and the process involved in undergoing risk assessment and genetic testing for breast and ovarian cancer? (Please circle)

1. Very knowledgeable
2. Somewhat knowledgeable
3. Not very knowledgeable
4. Not at all knowledgeable

4) If you chose to pursue risk assessment and genetic testing, how prepared would you feel?

1. Not at all prepared
2. Somewhat prepared
3. Quite prepared
4. Very prepared
5. Don't know
6. Refused

5) I am going to read a few statements. Please tell me which one best describes you.

1. I participated in a risk assessment and counseling program in the past 6 months.
2. I am planning to contact a risk assessment and genetic counseling program in the next 30 days.
3. I am planning to contact a risk assessment and genetic counseling program in the next 6 months.
4. I am thinking about contacting a risk assessment and genetic counseling program, but I'm not really sure and have made no specific plan.
5. I am not thinking about contacting a risk assessment and genetic counseling program.

Cancer Risk Concerns Survey

You called today because you have some concerns about your risk of developing **(refer to cancer site)** *breast/ovarian cancer. What things do you think contribute to your risk for breast/ovarian cancer?* **(Place an 'x' in the box(es) next to caller's response(s))**

Known Risks

- ☐ Age
- ☐ Early Menarche
- ☐ Late Menopause
- ☐ Family History/Genetics (BRCA 1 & 2)
- ☐ Personal History of Cancer
- ☐ Pregnancy/children
- ☐ Previous Breast Biopsies (particularly if it showed conditions known as atypical hyperplasia or lobular carcinoma in situ)

Possible Risks

- ☐ Lifestyle
  - ☐ Diet
  - ☐ Smoking
  - ☐ Exercise
  - ☐ Alcohol
  - ☐ Stress
- ☐ Personal Health History
  - ☐ HRT
  - ☐ DES
  - ☐ Abortion
  - ☐ Oral Contraceptives
- ☐ Environment
- ☐ Other (please specify)_____

(Use this sheet to review general risks after the baseline knowledge and perception survey) Those are (That is an) important factor(s) for us to discuss and I can provide you with information about your concern(s). First, I'd like to ask you some questions about what you have heard about risk factors for breast and ovarian cancer and then we will come back and discuss your concerns in depth.

Knowledge and Perception Survey

Please read all responses to caller. (Questions and statements read verbatim)

1) a.) In your opinion, compared to other women your own age, what are your chances of getting breast cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8
don't know	refused

b.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8
don't know	refused

2) a.) In your opinion, compared to other women your age who have a close relative with breast cancer, what are your chances of getting breast cancer some day?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8
don't know	refused

b.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8
don't know	refused

3) a.) During the past month, how often have you thought about your own chances of getting breast cancer (again)? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

b.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

4) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your mood? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

b.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

5) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your ability to perform your daily activities? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

b.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

6) *Breast and Ovarian Cancer Heredity Knowledge Scale: Please answer true or false to the following questions.*

	True	False	Don't know	Refused
Many women who do not have any of the known risk factors still get breast cancer	☐ 1	☐ 2	☐ 7	☐ 8
Over a lifetime, 1 out of 8 women will develop breast cancer	☐ 1	☐ 2	☐ 7	☐ 8
Women who are over 50 years of age are more likely to get breast cancer than are younger women	☐ 1	☐ 2	☐ 7	☐ 8
A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8
Early detection means a greater chance of surviving breast cancer	☐ 1	☐ 2	☐ 7	☐ 8
Women over age 40 should have mammograms at least every two years	☐ 1	☐ 2	☐ 7	☐ 8
A woman whose mother was diagnosed with breast cancer at age 69 is considered to be at high familial risk for breast cancer	☐ 1	☐ 2	☐ 7	☐ 8
A woman can inherit breast cancer gene mutations from her father	☐ 1	☐ 2	☐ 7	☐ 8
Most women who develop breast cancer do not have a family history of the disease	☐ 1	☐ 2	☐ 7	☐ 8
Ovarian cancer and breast cancer in the same family can be a sign of hereditary cancer	☐ 1	☐ 2	☐ 7	☐ 8

Testing for breast cancer gene mutations can tell a woman if she has breast cancer	☐ 1	☐ 2	☐ 7	☐ 8
Men cannot inherit breast cancer gene mutations	☐ 1	☐ 2	☐ 7	☐ 8
If there are other types of cancer in my family, I may have a higher than average risk of developing breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8
The process of risk assessment and genetic testing is simple, involving only a physical exam and blood test	☐ 1	☐ 2	☐ 7	☐ 8
One of the advantages of risk assessment and genetic testing is that finding out your risk can help you make decisions about pursuing risk reduction options, such as surgery and medications	☐ 1	☐ 2	☐ 7	☐ 8
There are no real disadvantages to pursuing risk assessment and genetic testing	☐ 1	☐ 2	☐ 7	☐ 8
A woman who develops breast cancer at an early age is more likely to have inherited breast cancer	☐ 1	☐ 2	☐ 7	☐ 8

Review of General Risks

Information Specialist will refer to the Cancer Risks Concerns Survey (p. 2) to review general risks using NCI materials.

Thank you for answering those questions. Now let's go back to your concerns about cancer risks. You mentioned that .....is/are risk factors. And you're correct. But some other things you should know about include...(**Mention proven risk factors NOT mentioned by caller as well as HRT and OC, then clarify any misconceptions the caller might have) Use WYNTK Breast as reference.**

****Place a check mark in all risk factors you addressed that the caller did not mention****

Known Risks (Specialist must mention all of these)

- ☐ Age*
- ☐ Early Menarche (before age 12)*
- ☐ Late Menopause (after age 55)*
- ☐ Family History/Genetics (BRCA 1 & 2)*
- ☐ Personal History of Cancer*
- ☐ Pregnancy/children (having first child after age 30 or having no children)*
- ☐ Previous Breast Biopsies **(particularly if it showed conditions known as atypical hyperplasia or lobular carcinoma in situ)*

Possible Risks (Specialist MUST mention HRT & OC in addition to addressing any concerns mentioned in this section by the caller – e.g., *there is some suggestion that alcohol may increase a woman's chance of getting breast cancer)*

Scientists are exploring other possible risks for breast cancer. For example, they're trying to determine whether taking birth control pills or hormone replacement therapy for post-menopausal symptoms increases a woman's risk of getting breast cancer. They hope to find the answer by studying a large number of women taking part in hormone related research. If you have questions about these and other possible risks, it might be helpful to discuss them with your doctor or other health care provider.

- ☐ HRT*
- ☐ Oral Contraceptives*

Comments

Are there any questions or concerns you have about these risk factors?

Review of Sporadic, Familial and Inherited Cancer Patterns

Now I'd like to give you some information about the different ways cancer can occur. There are three patterns of cancer: sporadic, familial and hereditary. **(Read descriptions verbatim)**

Sporadic - ***Most breast cancers, about 70% are sporadic. That means that these cancers happen by chance as a result of changes in a woman's body that occur during her lifetime.***

Familial - ***In about 20% of breast cancer cases, there is already a pattern of breast cancer in a woman's family. These cancer patterns are called familial. The other members of these families have an increased risk of breast cancer. The risk of breast cancer may be higher in these families because of similar environments that family members share or because of an inherited susceptibility.***

Hereditary - ***There are cancer patterns in which the family history is so strong that it appears members of the family may be inheriting a certain gene, or combination of genes, that puts them at greater risk for cancer. These cancer patterns are called hereditary.***
About 10% of all breast cancers fall into the hereditary cancer pattern.

(Information Specialist will check caller's understanding)

Today we've discussed risk factors for breast and ovarian cancer as well as the different types of cancer patterns. As I said in the beginning of the call, I can send you all this information. The materials I'll be sending will address everything we've talked about today. They will also go into greater detail on some of the things I've only mentioned briefly. Do you have any questions about what we've discussed today?

Would you be interested in a referral to a risk counseling/genetic testing program?

(1) ☐ YES (2) ☐ NO

If YES: Give regional referral. Please note which referrals were given.

1. _____
2. _____
3. _____
4. _____
5. _____

By the way, the packet of information will include a list of risk assessment and genetic testing facilities in the Pennsylvania, New Jersey, and Delaware region.

Before we conclude this call we have just a few last questions we would like to ask you. The next couple of questions are regarding your current preventive practices. Once again please be assured that all information provided is kept confidential.

(Questions read verbatim)

1. *How often do you perform Breast Self Exam (BSE)?*

(10) ☐ more than once a week
(20) ☐ at least once a week
(30) ☐ a couple of times a month
(40) ☐ at least once a month
(50) ☐ a few times each year
(60) ☐ at least once a year
(70) ☐ almost never
(80) ☐ never
(97) ☐ don't know
(98) ☐ refused

2. *How often do you go for mammograms?*

(1) ☐ once every few months
(2) ☐ a couple of times each year
(3) ☐ once a year
(4) ☐ once every few years
(5) ☐ almost never
(6) ☐ never
(7) ☐ don't know
(8) ☐ refused

3. **(For ovarian cancer callers only)** *In the past six months:*

How many transvaginal ultrasounds have you had? _____ (98) ☐ Refused ☐ N/A
How many pelvic exams have you had? _____ (98) ☐ Refused ☐ N/A
How many CA 125 blood tests have you had? _____ (98) ☐ Refused ☐ N/A

Information specialist will read all responses to the caller.

4. *Which of the following categories bests describes you? Are you:*

(10) ☐ Asian or Pacific Islander
(20) ☐ African American/Black
(30) ☐ Hispanic
(40) ☐ American Indian/Alaskan Native
(50) ☐ White
(60) ☐ Other
(98) ☐ Refused

1. *May we ask what is the highest level of education you have achieved?*

(1) ☐ Grade School
(2) ☐ Some High School
(3) ☐ High School Graduate
(4) ☐ Some College
(5) ☐ College Graduate
(6) ☐ Post-Graduate
(8) ☐ Refused

Information specialist will read all responses to the caller.

6. *How satisfied do you feel with the information you received today?*

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

don't know	refused
7	8

7. *To what extent would you recommend that others contact the Cancer Information Service for this information?*

definitely not	probably not	maybe	probably	definitely
1	2	3	4	5

don't know	refused
7	8

End Time _____

Complete ECRF. Remember to enter ECRF number on both forms: the intervention and the informed consent.

Thank you for calling the Cancer Information Service. I will send the information we've discussed. Is there anything else I can help you with today?

Appendix 4

ECRF # _____

Staff ID _____

Date _____

ENHANCED INTERVENTION

Start Time _____

(Follows informed consent document)

Caller is asking about: ☐ Breast Cancer ☐ Ovarian Cancer ☐ Both

Let me begin by asking just a few short questions:

1) Have you ever been diagnosed with cancer? ☐ YES ☐ NO ☐ Don't Know ☐ Refused

If yes - What kind of cancer were you diagnosed with? ***Age (at diagnosis)?*** _____

If no, continue with question 2.

2) Have you ever pursued risk assessment services? ☐ YES ☐ NO

If yes – When?

If no, continue with question 3.

Please read all responses for the following questions. (Questions read verbatim)

3) At this point, how would you rate your knowledge about breast and ovarian cancer risks and the process involved in undergoing risk assessment and genetic testing for breast and ovarian cancer? (Please circle)

5. Very knowledgeable
6. Somewhat knowledgeable
7. Not very knowledgeable
8. Not at all knowledgeable

4) If you chose to pursue risk assessment and genetic testing, how prepared would you feel?

7. Not at all prepared
8. Somewhat prepared
9. Quite prepared
10. Very prepared
11. Don't know
12. Refused

5) I am going to read a few statements. Please tell me which one best describes you.

1. I participated in a risk assessment and counseling program in the past 6 months.
2. I am planning to contact a risk assessment and genetic counseling program in the next 30 days.
3. I am planning to contact a risk assessment and genetic counseling program in the next 6 months.
4. I am thinking about contacting a risk assessment and genetic counseling program, but I'm not really sure and have made no specific plan.
5. I am not thinking about contacting a risk assessment and genetic counseling program.

Cancer Risk Concerns Survey

You called today because you have some concerns about your risk of developing **(refer to cancer site)** *breast/ovarian cancer. What things do you think contribute to your risk for breast/ovarian cancer?* **(Place an 'x' in the box(es) next to caller's response(s))**

Known Risks

- ☐ Age
- ☐ Early Menarche
- ☐ Late Menopause
- ☐ Family History/Genetics (BRCA 1 & 2)
- ☐ Personal History of Cancer
- ☐ Pregnancy/children
- ☐ Previous Breast Biopsies (particularly if it showed conditions known as atypical hyperplasia or lobular carcinoma in situ)

Possible Risks

- ☐ Lifestyle
  - ☐ Diet
  - ☐ Smoking
  - ☐ Exercise
  - ☐ Alcohol
  - ☐ Stress
- ☐ Personal Health History
  - ☐ HRT
  - ☐ DES
  - ☐ Abortion
  - ☐ Oral Contraceptives
- ☐ Environment
- ☐ Other (please specify)_____

(Use this sheet to review general risks after the baseline knowledge and perception survey)

Those are (That is an) important factor(s) for us to discuss and I can provide you with information about your concern(s). First, I'd like to ask you some questions about what you

have heard about risk factors for breast and ovarian cancer and then we will come back and discuss your concerns in depth.

Knowledge and Perception Survey

Please read all responses to caller. (Questions and statements read verbatim)

1) a.) In your opinion, compared to other women your own age, what are your chances of getting breast cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8
don't know	refused

b.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8
don't know	refused

2) a.) In your opinion, compared to other women your age who have a close relative with breast cancer, what are your chances of getting breast cancer some day?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8
don't know	refused

b.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8
don't know	refused

3) a.) During the past month, how often have you thought about your own chances of getting breast cancer (again)? Would you say… **[READ LIST]**

Not at all or rarely.....1

Sometimes.....2
Often.....3
A lot.....4

b.)How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

3) a.) During the past month, how often have thoughts about your chances of getting breast (again) affected your mood? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

b.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

4) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your ability to perform your daily activities? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

b.)How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

6) *Breast and Ovarian Cancer Heredity Knowledge Scale: Please answer true or false to the following questions.*

	True	False	Don't know	Refused
Many women who do not have any of the known risk factors still get breast cancer	☐ 1	☐ 2	☐ 7	☐ 8
Over a lifetime, 1 out of 8 women will develop breast cancer	☐ 1	☐ 2	☐ 7	☐ 8
Women who are over 50 years of age are more likely to get breast cancer than are younger women	☐ 1	☐ 2	☐ 7	☐ 8
A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8
Early detection means a greater chance of surviving breast cancer	☐ 1	☐ 2	☐ 7	☐ 8
Women over age 40 should have mammograms at least every two years	☐ 1	☐ 2	☐ 7	☐ 8
A woman whose mother was diagnosed with breast cancer at age 69 is considered to be at high familial risk for breast cancer	☐ 1	☐ 2	☐ 7	☐ 8
A woman can inherit breast cancer gene mutations from her father	☐ 1	☐ 2	☐ 7	☐ 8
Most women who develop breast cancer do not have a family history of the disease	☐ 1	☐ 2	☐ 7	☐ 8
Ovarian cancer and breast cancer in the same family can be a sign of hereditary cancer	☐ 1	☐ 2	☐ 7	☐ 8

Testing for breast cancer gene mutations can tell a woman if she has breast cancer	☐ 1	☐ 2	☐ 7	☐ 8
Men cannot inherit breast cancer gene mutations	☐ 1	☐ 2	☐ 7	☐ 8
If there are other types of cancer in my family, I may have a higher than average risk of developing breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8
The process of risk assessment and genetic testing is simple, involving only a physical exam and blood test	☐ 1	☐ 2	☐ 7	☐ 8
One of the advantages of risk assessment and genetic testing is that finding out your risk can help you make decisions about pursuing risk reduction options, such as surgery and medications	☐ 1	☐ 2	☐ 7	☐ 8
There are no real disadvantages to pursuing risk assessment and genetic testing	☐ 1	☐ 2	☐ 7	☐ 8
A woman who develops breast cancer at an early age is more likely to have inherited breast cancer	☐ 1	☐ 2	☐ 7	☐ 8

Review of General Risks

Information Specialist will refer to the Cancer Risks Concerns Survey (p. 2) to review general risks using NCI materials.

Thank you for answering those questions. Now let's go back to your concerns about cancer risks. You mentioned that .....is/are risk factors. And you're correct. But some other things you should know about include...(Mention proven risk factors NOT mentioned by caller as well as HRT and OC, then clarify any misconceptions the caller might have) Use WYNTK Breast as reference.

****Place a check mark in all risk factors you addressed that the caller did not mention****

Known Risks (Specialist must mention all of these)

- ☐ Age*
- ☐ Early Menarche (before age 12)*
- ☐ Late Menopause (after age 55)*
- ☐ Family History/Genetics (BRCA 1 & 2)*
- ☐ Personal History of Cancer*
- ☐ Pregnancy/children (having first child after age 30 or having no children)*
- ☐ Previous Breast Biopsies *(particularly if it showed conditions known as atypical hyperplasia or lobular carcinoma in situ)*

Possible Risks (Specialist MUST mention HRT & OC in addition to addressing any concerns mentioned in this section by the caller – e.g., *there is some suggestion that alcohol may increase a woman's chance of getting breast cancer*)

Scientists are exploring other possible risks for breast cancer. For example, they're trying to determine whether taking birth control pills or hormone replacement therapy for post-menopausal symptoms increases a woman's risk of getting breast cancer. They hope to find the answer by studying a large number of women taking part in hormone related research. If you have questions about these and other possible risks, it might be helpful to discuss them with your doctor or other health care provider.

- ☐ HRT*
- ☐ Oral Contraceptives*

Comments

Are there any questions or concerns you have about these risk factors?

Review of Basic Genetics and Cancer (Verbatim)

There are a few facts you should know about the role of genes in the development of cancer, particularly in the development of breast and ovarian cancers

- *You get half your genes from your mother and the other half from your father.*
- *People with hereditary breast and ovarian cancer have inherited a changed or mutated gene from one of their parents. But they still have one normal copy of the gene from the other parent.*
- *Something needs to occur to the normal gene before a cancer will develop. That explains why not all people with cancer gene mutations get cancer – nothing ever happened to alter the normal gene.*
- *Scientists are beginning to identify which of our genes are related to cancer. So far, they have identified two genes which, when altered, can cause breast and ovarian cancer. One gene is known as BRCA 1. It appears to cause cancers in the breast and ovaries. Another gene, BRCA 2, was also identified. It appears to cause mainly breast cancer, but it may also cause ovarian and prostate cancers. BRCA 2 is believed to be responsible for some cases of breast cancer in men.*

Review of Sporadic, Familial and Inherited Cancer Patterns

Now I'd like to give you some information about the different ways cancer can occur. There are three patterns of cancer: sporadic, familial and hereditary. **(Read descriptions verbatim)**

Sporadic - ***Most breast cancers, about 70% are sporadic. That means that these cancers happen by chance as a result of changes in a woman's body that occur during her lifetime.***

Familial - ***In about 20% of breast cancer cases, there is already a pattern of breast cancer in a woman's family. These cancer patterns are called familial. The other members of these families have an increased risk of breast cancer. The risk of breast cancer may be higher in these families because of similar environments that family members share or because of an inherited susceptibility.***

Hereditary - ***There are cancer patterns in which the family history is so strong that it appears members of the family may be inheriting a certain gene, or combination of genes, that puts them at greater risk for cancer. These cancer patterns are called hereditary.***
About 10% of all breast cancers fall into the hereditary cancer pattern.

(Information Specialist will check caller's understanding)

Review of Hallmarks of Inherited Breast/Ovarian Cancer

There are several characteristics or signs that help determine if a cancer fits a hereditary pattern. These are:

1. ***The number of relatives with breast cancer.*** The more relatives there are in the family with breast cancer, the more likely it is to be a hereditary pattern. Also, both your mother and father's sides of the family are important since the altered gene can be passed down through either side.
2. ***Occurrence in every generation.*** In the hereditary cancer pattern, there is usually someone in each generation who develops the disease. So, if a woman's sister, mother and maternal grandmother (mother's mother) all had breast cancer, it is most likely a hereditary pattern. There are some exceptions. For example, the *altered* gene is just as likely to be passed on to a son as to a daughter. Since males don't usually get breast cancer, it can skip his generation, making the pattern harder to see. He can, however, pass the gene on to his children.
3. ***Occurrence of other cancers in the family.*** There are a few other types of cancer associated with the hereditary pattern of breast cancer. They are ovarian cancer in women and prostate cancer in men.
4. ***The age when the cancer occurs.*** Most breast cancers occur in women aged 50 or older. In fact, a woman's chance of getting breast cancer increases with age. One in eight women will develop breast cancer in her lifetime and most of those cancers will be sporadic, or caused by chance. When there is a hereditary pattern, the cancer sometimes occurs at younger ages, in the 30's or 40's. The same may be true for ovarian cancer if it is part of a hereditary pattern.
5. ***Breast cancers that occur in both breasts.*** This is called *bilateral* breast cancer. The woman who gets cancer in both breasts instead of just one tend to fit into the hereditary cancer pattern.
6. ***Jewish Ancestry.*** While it is not known whether breast cancer is more prevalent in women of Ashkenazi (Eastern European) Jewish descent than in the general population, researchers recently identified specific gene alterations which are particularly prevalent in this population.

(Information Specialist will check caller's understanding)

Family Cancer History

We've talked about family history as a risk factor for breast and ovarian cancers. We've also discussed different cancer patterns and some of the signs or characteristics that could indicate an inherited cancer. One of the first steps a person would need to take to find out more about her personal risk for hereditary cancer would be to obtain as complete a family cancer history as possible. I am not a genetic counselor or a doctor and I certainly cannot interpret your risk over the phone. But what I'd like to do is to ask some questions about your family history that I'll send to you. You might want to take this information to your health care provider so the two of you can discuss any concerns you might have about your risk and whether or not risk assessment services would be appropriate for you. I'd like to begin by asking you some questions about your family history that include their relationship to you, their age when they were diagnosed, their current age (if they're still alive) and the kind of cancer they had.

(If caller has a history of cancer, begin with her and recap the information given previously. Otherwise, begin with the immediate family. E.g., *Has anyone in your immediate family ever been diagnosed with cancer? How about your mother? Anyone else – father, siblings, children? Did anyone on your mother's side ever have cancer? Etc.*)
Probe Immediate family, mother's side, father's side.

	Breast Cancer Age at diagnosis:	Ovarian Cancer Age at diagnosis:	Colon Cancer Age at diagnosis:	Other (Specify) Age at diagnosis:	Unknown	No Cancer
Mother Current Age						
Father Current Age						
Sister(s) Current Age						
Brother(s) Current Age						
Children Current Age						

Mother's Side

	Breast Age at dx	Ovarian Age at dx	Colon Age at dx	Other Age at dx	Unknown	No Cancer
Grandmother Age:						
Grandfather Age:						
Aunt(s) Age:						
Uncle(s) Age:						
Cousin(s) Age						

Father's Side

	Breast Age at dx	Ovarian Age at dx	Colon Age at dx	Other Age at dx	Unknown	No Cancer
Grandmother Age:						
Grandfather Age:						
Aunt(s) Age:						
Uncle(s) Age:						
Cousin(s) Age:						

Challenges in Interpreting Family History Information

(Read verbatim)

You should be aware that there are many challenges in interpreting family history information and sometimes it can be very difficult to make a determination about whether the cancer in the family appears to be sporadic, familial or hereditary. For example, if the family was very small or if information on several people is missing, it would be hard to find a hereditary pattern even if one exists. For these reasons, it is important to talk to your doctor, or a professional trained in genetics, such as a genetic counselor.

(Information Specialist will summarize and check caller's understanding)

Process and Services (new field)

Let's talk now about what happens when a woman goes for risk assessment, high risk counseling and/or genetic testing? What have you heard is involved in such programs?
(Please place an 'x' next to all that apply)

Caller	IS	
(10)☐	☐	Counseling
(20)☐	☐	Family history (pedigree)
(30)☐	☐	Information/Education (group and/or individual sessions)
(40)☐	☐	Blood work for BRCA 1/2 (Perhaps. * Testing is not done without counseling. Results are never back the same day. *)
(50)☐	☐	Medical records (perhaps)
(60)☐	☐	A process (often takes place over a period of time)
(70)☐	☐	Screening (mammography, CA125, BSE, etc)
(80)☐	☐	Multidisciplinary Team (they'll be seen by more than one health professional)
(90)☐	☐	Other (please write in) _____

Many of the things you've mentioned are involved in risk assessment and genetic testing. Other things you should know about participating in any risk assessment program include:

Mention anything not checked and place a check mark in the corresponding box.

Clarify misconceptions using NCI materials

Comments

Note all of the following:

- ☐ *Programs vary from institution to institution*
- ☐ *It is important to know why risk assessment and genetic testing are important to you as well as how the information will change your behavior.*
- ☐ *Cost may be expensive if not done as part of research*
- ☐ *You might not get test results if you are part of a research study*
- ☐ *Insurance might not cover the risk assessment/counseling services or the testing*
- ☐ *It might take some time to get an appointment (That's OK)*

☐ *Should you decide to get tested, results may not be available for some time (up to 2 years)*

Pros and Cons of Risk Assessment/Genetic Testing **(new field)**

From your perspective, what are the advantages of risk assessment and genetic testing?
(Please place an 'x' next to all that apply)

(10)**Risk Assessment**

Caller	**IS**	
(11)☐	☐	Gain information about personal familial risk
(12)☐	☐	Increase understanding of risk factors for cancer
(13)☐	☐	Help in deciding whether or not to undergo genetic testing

(20)**Risk Assessment/Genetic Testing**

(21)☐	☐	Acquire information that can help make lifestyle changes
(22)☐	☐	Make plans to increase or change surveillance and/or screening (e.g., more frequent mammograms, BSE) – *Currently, the National Cancer Institute recommends regular mammograms for women over age 40 (every 1-2 years). Women at increased risk might require more frequent mammograms.*
(23)☐	☐	Information for the entire family
(24)☐	☐	Contributes to research
(25)☐	☐	Help make child-bearing decisions
(26)☐	☐	Relieve self and family of worry and anxiety about risk

(30)**Genetic Testing**

(31)☐	☐	Confirm whether or not gene -/+
(32)☐	☐	Help decide whether or not to pursue preventive treatments (e.g., mastectomy, oophorectomy, tamoxifen)
(33)☐	☐	Other (please write in) _____

Yes. Some other advantages include: **(mention those not checked)**

From your perspective, what do you think are the disadvantages of risk assessment and genetic testing?(new field) **(Please check all that apply and place a check mark in the corresponding box)**

(10)☐	☐	Insurance (Health and/or Life) – inability to obtain or loss of
(11)☐	☐	Employment discrimination
(12)☐	☐	Confidentiality
(13)☐	☐	No guaranteed way to prevent cancer
(14)☐	☐	Survivor's guilt

(15)☐	☐	Cost
(16)☐	☐	Guilt re: the possibility of passing on a + gene to one's children
(17)☐	☐	Might have a negative impact on the family
(18)☐	☐	May be harder to cope with cancer risk if you know the test results
(19)☐	☐	Negative test results may lead to a false sense of security
(20)☐	☐	Test results may be indeterminate
(21)☐	☐	Tests may not be able to precisely determine risk
(22)☐	☐	Don't trust modern medicine
(90)☐	☐	Other (please write in) _____

Yes. Some other disadvantages include: **(mention those not checked and place a check mark in the corresponding box.)**

Comments

(Information Specialist will check caller's understanding)

We've discussed many things today - cancer risks, the different kinds of cancer patterns, basic cancer genetics as well as what's involved in risk assessment, risk counseling and genetic testing. As I said in the beginning of the call, I can send you all this information. The materials I'll be sending will address everything we've talked about today. They will also go into greater detail on some of the things I've only mentioned briefly. Do you have any questions about what we've discussed today? Would you be interested in a referral to a risk counseling/genetic testing program?

(1) ☐ YES (2) ☐ NO

If YES: Give regional referral. Please note which referrals were given.

1. _____
2. _____
6. _____
7. _____
8. _____

By the way, the packet of information will include a list of risk assessment and genetic testing facilities in the Pennsylvania, New Jersey, and Delaware region.

Before we conclude this call we have just a few last questions we would like to ask you. The next couple of questions are regarding your current preventive practices. Once again please be assured that all information provided is kept confidential.

(Questions read verbatim)

1. *How often do you perform Breast Self Exam (BSE)?*

(10) ☐ more than once a week
(20) ☐ at least once a week
(30) ☐ a couple of times a month
(40) ☐ at least once a month
(50) ☐ a few times each year
(60) ☐ at least once a year
(70) ☐ almost never
(80) ☐ never
(97) ☐ don't know
(98) ☐ refused

2. *How often do you go for mammograms?*

(1) ☐ once every few months
(2) ☐ a couple of times each year
(3) ☐ once a year
(4) ☐ once every few years
(5) ☐ almost never
(6) ☐ never
(7) ☐ don't know
(8) ☐ refused

3. **(For ovarian cancer callers only)** In *the past six months:*

How many transvaginal ultrasounds have you had? _____ (98) ☐ Refused ☐N/A
How many pelvic exams have you had? _____ (98) ☐ Refused ☐N/A
How many CA 125 blood tests have you had? _____ (98) ☐ Refused ☐N/A

Information specialist will read all responses to the caller.

4. *Which of the following categories bests describes you? Are you:*

(10) ☐ Asian or Pacific Islander
(20) ☐ African American/Black
(30) ☐ Hispanic
(40) ☐ American Indian/Alaskan Native
(50) ☐ White
(60) ☐ Other
(98) ☐ Refused

5. *May we ask what is the highest level of education you have achieved?*

(1) ☐ Grade School
(2) ☐ Some High School
(3) ☐ High School Graduate
(4) ☐ Some College
(5) ☐ College Graduate
(6) ☐ Post-Graduate
(8) ☐ Refused

Information specialist will read all responses to the caller.

6. *How satisfied do you feel with the information you received today?*

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

don't know	refused
7	8

7. *To what extent would you recommend that others contact the Cancer Information Service for this information?*

definitely not	probably not	maybe	probably	definitely
1	2	3	4	5

don't know	refused
7	8

End Time _____

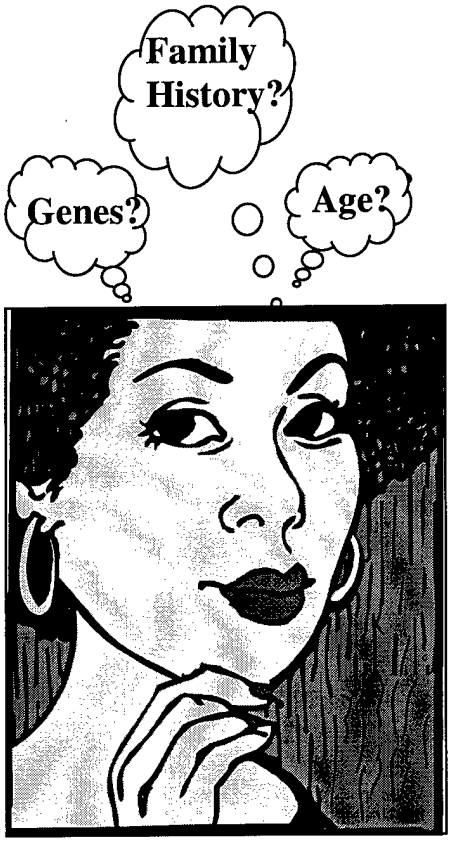
Complete ECRF. Remember to enter ECRF number on both forms: the intervention and the informed consent.

Thank you for calling the Cancer Information Service. I will send the information we've discussed. Is there anything else I can help you with today?

Appendix 5.

Are you concerned about your risk for Breast Cancer or Ovarian Cancer?

- Do you have questions about breast or ovarian cancer?
- Are you concerned about your personal cancer risk or the risks for others in your family?
- Are you interested in finding out more about genetic counseling & genetic testing?



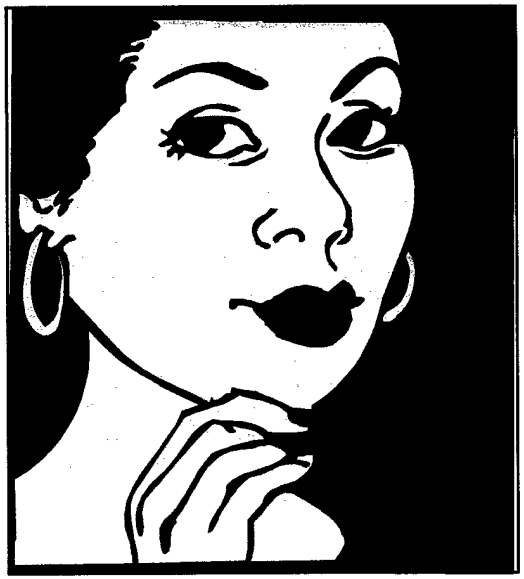
Please call The National Cancer Institute's
Cancer Information Service at
1-800-4-CANCER
for more information

CANCER INFORMATION SERVICE
A PROGRAM OF THE NATIONAL CANCER INSTITUTE

FOX CHASE CANCER CENTER

Appendix 6. Brochure

Do you have questions about breast or ovarian cancer?



- Are you concerned about your personal cancer risk or the risks for others in your family?

- Are you interested in finding out more about genetic counseling & genetic testing?

Please call The National Cancer Institute's
Cancer Information Service at
1-800-4-CANCER
for more information

CANCER INFORMATION SERVICE™

A PROGRAM OF THE NATIONAL CANCER INSTITUTE
YOUR LINK TO CANCER INFORMATION

1 800 4 CANCER

When you need:
- answers to your questions about cancer
- tips for preventing cancer
- help with quitting smoking
- publications and community resources
- assistance with cancer education efforts

Call the National Cancer Institute's Cancer Information Service, your source for the latest, most accurate cancer information.

The Cancer Information Service assists:
- cancer patients and family members
- general public
- health professionals
- state and regional organizations

Call our nationwide toll-free telephone service to receive personalized answers to your questions in English or Spanish.

Contact our partnership program staff to enhance your organization's cancer education efforts.

Visit the National Cancer Institute's Web site at http://www.nci.nih.gov.

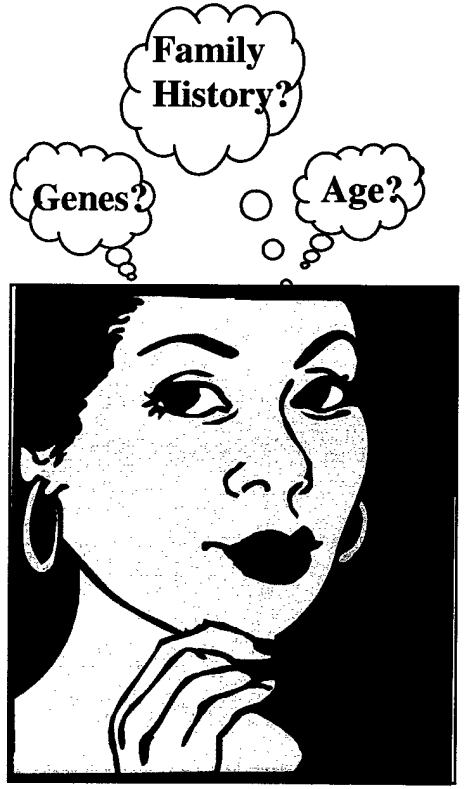
1-800-4-CANCER (1-800-422-6237)
Monday through Friday, 9 a.m. to 4:30 p.m. local time
TTY equipment: 1-800-332-8615

CANCER INFORMATION SERVICE™

A PROGRAM OF THE NATIONAL CANCER INSTITUTE
YOUR LINK TO CANCER INFORMATION

FOX CHASE
CANCER CENTER

Are you concerned about your risk for Breast Cancer or Ovarian Cancer?



The National Cancer Institute's Cancer Information Service
1-800-4-CANCER

Appendix 7

DOD COURSE EVALUATION QUESTIONS

1. Course Contents

Please check or circle the correct answer.

	True	False
1. The BRCA1 mutation is an example of a germline mutation.		
2. The term penetrance refers to the likelihood that the presence of a mutated gene will actually result in disease.		
3. Autosomal recessive disorders develop in persons who inherit one copy of the mutant gene, from either parent.		
4. In familial cancer patterns, more than one type of cancer is present in the family and several family members are usually affected.		
5. Relative risk refers to the rate of new breast cancer cases during a given period of time, in a given population.		
6. At least a three-generation pedigree should be obtained when taking a cancer family history.		
7. The Gail risk model will overestimate risk in women with an extensive family history.		
8. Three distinct mutations on the BRCA1 gene have been identified in women of Ashkenazi Jewish descent.		
9. A woman with a true negative test result has the same risk of developing breast or ovarian cancer as other women in the general population.		
10. Life insurance companies may not use knowledge of a genetic predisposition to cancer in underwriting decisions.		

11. The Gail model calculates risk on all of the following factors except:
    a. The woman=s current age.
    b. The woman=s age at first menarche.
    c. The number of 1st and 2nd degree relatives.
    d. The number of breast biopsies.
    e. The woman=s age at 1st live birth.

12. All of the following are hallmarks of inherited breast cancer except:
    a. Breast and ovarian cancer in the same woman.
    b. Early onset of breast or ovarian cancer.
    c. Multiple cases of breast cancer.
    d. Early death of affected members from cancer.
    e. Occurrences of other cancers in the family.

13. Which of the following most influences an individual=s perception of risk?
    a. Perceptions about the disease.
    b. Educational level.
    c. Personal and family experience.
    d. Cultural, social, and religious factors
    e. Personality traits.

14. Which of the following risk models calculates for the presence of a BRCA mutation?
    a. The Gail model.
    b. The Claus model.
    c. Both the Gail & Claus model.
    d. None of the above.

15. Genetic testing results may be expressed as:
    a. Positive, negative, indeterminate, inconclusive
    b. Positive, negative, unknown, inconclusive
    c. Positive, negative, undetermined, inconclusive
    d. Positive, negative, indeterminate, nonspecific

16. All of the following are limitations of genetic testing except:
    a. Finding an alteration can indicate increased risk of developing cancer, but it can not indicate if or when cancer will develop.
    b. If you are a carrier, there is much uncertainty about recommended preventative steps and their value.
    c. If an inherited gene is to blame, it is always either the BRCA1 or BRCA2 genes.
    d. In some families, multiple cases of cancer may reflect shared environmental exposures rather than genetic susceptibility.

17. If a woman tests positive for a BRCA1 or BRCA2 mutation,
    her children have a ___% chance of having inherited this mutation.
    a. 30%
    b. 50%
    c. 75%
    d. 90%

18. Which of the following are considered ethical and/or legal concerns

related to genetic testing for cancer susceptibility?

a. Informed consent
b. Privacy and confidentiality
c. Discrimination issues
d. All of the above

19. The Health Insurance Portability & Accountability Act ensures all of the following except:

a. Americans have access to group insurance when they change jobs.
b. Medical information from genetic tests cannot be used to deny coverage to individuals seeking new health insurance.
c. Life insurance companies cannot deny coverage based on the results of genetic tests.
d. Prohibits health plans from charging higher premiums to an individual than to others in the group.

In the following questions, you are asked to make inferences from the information provided. Read the following case study and develop a matching pedigree in the space below.

BH, a 38 year old single woman of Italian, Jewish ancestry, is seeking a referral for genetic testing because of a family history of breast cancer:

< Her mother was diagnosed with breast cancer at age 48 and died at age 55.
< Her mother had 4 siblings;
  < a sister who was diagnosed with breast cancer at age 56 and died at age 63;
  < another sister who died from an unknown condition at an unknown age;
  < a sister who was diagnosed with ovarian cancer at age 51 and is still alive at age 58;
  < and a brother who is alive and well at age 61.
< BH=s maternal grandmother was diagnosed with breast cancer at age 62 and died 2 years later.
< BH has 2 other siblings, a brother and a sister. Her older sister was diagnosed at age 40 with breast cancer and developed ovarian cancer three years later. She is still alive at age 44. Her brother is alive and well at age 36.

20. Based on BH=s pedigree, what cancer pattern does her family most represent?

a. Familial
b. Hereditary
c. Sporadic
d. Unable to determine

21. When considering genetic testing, who else in BH=s family should be tested?

a. Her aunt and uncle
b. Her aunt only
c. Her aunt and/or sister
d. Her sister only

II. Training Assessment

Using a scale from 1 (Not at all) to 5 (Very much), please indicate your response to the following questions:

	Not at all		**Somewhat**		**Very Much**
This training has improved my understanding of genetics.	1	2	3	4	5
I feel more confident in discussing the issues related to inherited breast and ovarian cancer to callers.	1	2	3	4	5
This training has strengthened my knowledge of the genetic counseling process.	1	2	3	4	5
I can explain the relationship between gene mutations and cancer to callers with greater confidence.	1	2	3	4	5
This training has improved my skill level in explaining the issues related to genetic testing.	1	2	3	4	5

III. Follow-up

Name three skills that you have gained or strengthened as a result of the training?

_____

_____

_____

What three things are you going to do to further develop your skills surrounding genetics, inherited risk, and genetic testing?

_____

_____

_____

What one thing are you going to do differently on your calls as a result of this training?

_____

_____

_____

THANK YOU

Appendix 8

Revised Training Curriculum

Introduction
- Background on the DOD Grant
- Training
  - Purpose

The Role of Genes in Cancer
- Identify genes responsible for breast and ovarian cancer
- BRCA1
- BRCA2

Cancer Patterns & Risk Assessment
- Sporadic, familial, and hereditary patterns
- Pedigrees
  - The importance of obtaining the family history

Inherited Risk
- Definitions
- Currently used risk models
  - Estimating risk
- Genetic Counseling & Services
  - The role of the genetic counselor
  - The range of programs & services
- Factors that influence risk perception
- Presenting risk information
  - The impact of cancer risk information

Genetic Testing & Informed Consent
- Considerations
- Who should be tested
- Reasons for testing
- Interpreting results
- Benefits, Risks, Limitations
- Ethical, legal and social issues
- Psychological issues
  - Ethnic and cultural issues
- Management strategies and follow-up

Study Procedures & Interventions
- Informed consent
- Randomization
- Computer program
- Mailouts
- Coding

Appendix 9

	STANDARD	ENHANCED
Assess Eligibility	Woman >18yo, calling about breast/ovarian cancer risk and/or risk assessment/genetic testing services.	Woman >18yo, calling about breast/ovarian cancer risk and/or risk assessment/genetic testing services.
Informed Consent	Are you willing to participate?	Are you willing to participate?
Study Implementation	General Information	General Information
	Assessment of Baseline Variables	Assessment of Baseline Variables
	Cancer Risks Concerns Survey	Cancer Risks Concerns Survey
	Breast/Ovarian Cancer Knowledge Scale	Breast/Ovarian Cancer Knowledge Scale
	Review of General Risks	Review of General Risks
		Basic Genetics and Cancer
	Cancer Patterns	Cancer Patterns
		Hallmarks of Inherited Disease
		Family Cancer History
		Challenges in Interpreting Family History Information
		Process and Services
		Pros and Cons
	Summation and Referral if appropriate	Summation and Referral if appropriate
	Concluding questions	Concluding questions
	Demographics	Demographics
Mailouts	WYNTK Breast & Ovarian Genetic Testing for Breast Cancer Risk - Pub & FS PDQ Cancer Genetics Services Directory	WYNTK Breast & Ovarian Genetic Testing for Breast Cancer Risk - Pub & FS PDQ Cancer Genetics Services Directory Understanding Gene Testing

Appendix 10

FOLLOW-UP ASSESSMENT TOOL - 2 Weeks

ECRF _____ Today's Date _____ Initial Survey Date _____ Start time of call _____

First Name _____ Last Name _____

Address_____ City _____ State ___ Zip Code _____

Subject ID: _____ Subject's Age _____ Subject's Race _____

Breast Cancer _____ Ovarian Cancer _____ Both_____

CIS Introduction: "Hello, may I speak to _____. (IF PERSON IS THERE, CONTINUE; IF NOT CALL BACK OR RESCHEDULE CALL). My name is _____ and I am a representative of the Fox Chase Cancer Center. I am calling as a follow up to a phone call you made to the Cancer Information Service. When you called the CIS, a few weeks ago, you agreed to participate in a study that examines different approaches to providing information to women about breast cancer risk, risk assessment/genetic testing. To help us evaluate our service, we would like to ask you to participate in a brief, 10 minute, interview which will assess your specific thoughts, feelings, and behaviors concerning your genetic risk for breast/ovarian cancer."

"Would now be a good time to ask you a few questions?"

___YES → move to Questions

___ NO → reschedule call

"When would you like to reschedule this interview?"

Day: _____ Time: _____

Follow-up Assessment Tool: "We would just like to ask you a few questions about your thoughts and feeling concerning risk assessment/genetic testing".

1) a.) In your opinion, compared to other women your own age, what are your chances of getting breast cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average
7	8	9		
don't know	refused	missing		

c.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average
7	8	9		
don't know	refused	missing		

2.) a.) In your opinion, compared to other women your age who have a close relative with breast cancer, what are your chances of getting breast cancer some day?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

8	8	9
don't know	refused	missing

c.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8	9
don't know	refused	missing

3) a.) During the past month, how often have you thought about your own chances of getting breast cancer (again)? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

c.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

5) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your mood? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

c.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

6) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your ability to perform your daily activities? Would you say... **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

c.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

To what degree would you agree with the following statements:

6. Risk assessment/genetic testing can help you better understand your risk for breast/ovarian cancer, so that you can make decisions about pursuing risk reduction approaches, such as surgery and/or medications (e.g., tamoxifen)?

1	2	3	4
strongly disagree	mildly disagree	mildly agree	strongly agree

7. Risk assessment/genetic testing can help you better understand your risk for breast/ovarian cancer, so that you can determine if you need to increase screening, such as mammography or transvaginal ultrasounds.

1	2	3	4
strongly disagree	mildly disagree	mildly agree	strongly agree

8. Risk assessment/genetic testing can jeopardize your insurance coverage?

1	2	3	4
strongly disagree	mildly disagree	mildly agree	strongly agree

9. Risk assessment/genetic testing can have a negative emotional impact on you and on your family?

1	2	3	4
strongly disagree	mildly disagree	Mildly agree	strongly agree

10. Breast Cancer Heredity Knowledge Scale: Please answer true or false to the following questions.

	True	False	Don't know	Refused	Missing
Many women who do not have any of the known risk factors still get breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Over a lifetime, 1 out of 8 women will develop breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Women who are over 50 years of age are more likely to get breast cancer than are younger women	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Early detection means a greater chance of surviving breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Women over age 40 should have mammograms at least every two years	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman whose mother was diagnosed with breast cancer at age 69 is considered to be at high familial risk for breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman can inherit breast cancer gene mutations from her father	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Most women who develop breast cancer do not have a family history of the disease	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Ovarian cancer and breast cancer in the same family can be a sign of hereditary cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Testing for breast cancer gene mutations can tell a woman if she has breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Men cannot inherit breast cancer gene mutations	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9

If there are other types of cancer in my family, I may have a higher than average risk of developing breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
The process of risk assessment/genetic testing is simple, involving only a physical exam and blood test	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
One of the advantages of risk assessment/genetic testing is that, finding out your risk can help you make decisions about pursuing risk reduction options, such as surgery and medications	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
There are no real disadvantages to pursuing risk assessment/genetic testing	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who doesn't have an altered BRCA1 gene can still get cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who develops breast cancer at an early age is more likely to have inherited breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9

11. At this point, how would you rate your knowledge about breast and ovarian cancer risks and the process involved in undergoing risk assessment/genetic testing for breast and ovarian cancer?

1. Very knowledgeable
2. Somewhat knowledgeable
3. Not very knowledgeable
4. Not at all knowledgeable

12. How would you describe your present behavior with regard to risk assessment and genetic testing for breast and ovarian cancer?

1. I have undergone risk assessment and genetic testing in the past 6 months (go to question 14)
2. I am planning to undergo risk assessment and genetic testing in the next 30 days (continue)
3. I am planning to undergo risk assessment and genetic testing in the next 6 months (continue)
4. I am thinking about undergoing risk assessment and genetic testing, but I'm not really sure and have made no specific plan (continue)
5. I am not thinking about undergoing risk assessment and genetic testing (continue)

13. If you decided to pursue risk assessment/genetic testing, how prepared would you be to undergo these procedures?

1	2	3	4

not at all prepared	somewhat prepared	quite prepared	very prepared

14. If you have already pursued risk assessment services, how prepared did you feel?

1	2	3	4
not at all prepared	somewhat prepared	quite prepared	very prepared

15. How satisfied do you feel with the information you received on the phone from the CIS?

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

Why or why not _____

_____

_____

16. How satisfied do you feel with the information you received by mail from the CIS?

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

Why or why not

_____

_____

_____

17. To what extent would you recommend that others contact the Cancer Information Services for this information?

definitely not	Probably not	maybe	probably	definitely
1	2	3	4	5

Why or why not _____

_____

_____

18. Was there anything particularly helpful about the information you received from the CIS, either by mail or over the phone? Please explain_____

19. Have you ever been diagnosed with benign breast disease?

(1) ☐ Yes (2) ☐ No (7) ☐ Don't know (8) ☐ Refused (9) ☐ Missing

20. Have you ever had a breast biopsy?

(1) ☐ YES (2) ☐ NO (7) ☐ Don't know (8) ☐ Refused (9) ☐ Missing

If YES: How many biopsies have you had? _____

21. Have you ever had a biopsy diagnosed as atypical hyperplasia? YES NO

22. Have you ever been diagnosed with ductal carcinoma in situ or lobular carcinoma in situ?

YES NO

23. At what age did you first start menstruating? _____ (97) ☐ don't know (98) ☐ refused (99) ☐ missing

24. Have you stopped menstruating? Yes (answer question 25) No (go to question 26)

25. At what age did you stop menstruating? _____ (97) ☐ don't know (98) ☐ refused (99) ☐ missing

26. Do you have any children? (1) ☐ Yes (2) ☐ No (7) ☐ Don't know (8) ☐ Refused (9) ☐ Missing

If YES: How old were you when your first child was born? _____ (98) ☐ Refused (99) ☐ Missing

How many children do you have?_____ (98) ☐ Refused (99) ☐ Missing

27. How many of your first degree relatives – mother, sister(s), and/or daughter(s) – have been diagnosed with breast cancer? _____

28. How many of your first degree relatives – mother, sister(s) and/or daughter(s) – have been diagnosed with ovarian cancer? _____

29. How often do you perform Breast Self Exam (BSE)?

____ more than once a week
____ at least once a week
____ a couple of times a month
____ at least once a month
____ a few times each year
____ at least once a year
____ almost never
____ never

30. How often do you go for mammograms?

____ once every few months
____ a couple of times each year
____ once a year
____ once every few years
____ almost never
____ never

31. **(For ovarian cancer callers only):** In the past six months:

How many transvaginal ultrasounds have you had? _____
How many pelvic exams have you had? _____
How many CA 125 blood test have you had? _____

32. Lastly, I will read to you 4 scenarios, each followed by statements describing what you might do in each situation. Please pick as many or as few statements as you like.

1. Vividly imagine that you are **afraid** of the dentist and have to get some dental work done. Which of the following would you do? Check **all** of the statements that might apply to you.

___ Would you ask the dentist exactly what he was going to do.

___ Would you take a tranquilizer or have a drink before going.
___ Would you try to think about pleasant memories.
___ Would you want the dentist to tell you when you would feel pain.
___ Would you try to sleep.
___ Would you watch all the dentist's movements and listen for the sound of the drill.
___ Would you watch the flow of water from your mouth to see if it contained blood.
___ Would you do mental puzzles in your mind.

2. Vividly imagine that you are being held hostage by a group of armed terrorists in a public building. Which of the following would you do? Check **all** statements that might apply to you.

___ Would you sit by yourself and have as many daydreams and fantasies as you could.
___ Would you stay alert and try to keep yourself from falling asleep.
___ Would you exchange life stories with the other hostages.
___ If there was a radio present, would you stay near it and listen to the bulletins about what the police were doing.
___ Would you watch every movement of your captors and keep an eye on their weapons.
___ Would you try to sleep as much as possible.
___ Would you think about how nice it's going to be when you get home.
___ Would you make sure you knew where every possible exit was.

3. Vividly imagine that, due to a large drop in sales, it is rumored that several people in your department at work will be laid off. Your supervisor has turned in an evaluation of your work for the past year. The decision about lay-offs has been made and will be announced in several days. Check **all** of the statements that might apply to you.

___ Would you talk to your fellow workers to see if they knew anything about what the supervisor's evaluation of you said.
___ Would you review the list of duties for your present job and try to figure out if you had fulfilled them all.
___ Would you go to the movies to take your mind off things.
___ Would you try to remember any arguments or disagreements you might have had with the supervisor that would have lowered his opinion of you.
___ Would you push all thoughts of being laid off out of your mind.
___ Would you tell your spouse that you'd rather not discuss your chances of being laid off.
___ Would you try to think which employees in your department the supervisor might have thought had done the worst job.
___ Would you continue doing your work as if nothing special was happening.

4. Vividly imagine that you are on an airplane, thirty minutes from your destination, when the plane unexpectedly goes into a deep dive and then suddenly levels off. After a short time, the pilot announces that nothing is wrong, although the rest of the ride may be rough. You, however, are not convinced that all is well. Check **all** of the statements that might apply to you.

___ Would you carefully read the information provided about safety features in the plane and make sure you knew where the emergency exits were.
___ Would you make small talk with the passenger beside you.
___ Would you watch the end of the movie, even if you had seen it before.
___ Would you call for the stewardess and ask her exactly what the problem was.
___ Would you order a drink or tranquilizer from the stewardess.

___ Would you listen carefully to the engines for unusual noises and watch the crew to see if their behavior was out of the ordinary.
___ Would you talk to the passenger beside you about what might be wrong.
___ Would you settle down and read a book or magazine or write a letter.

Thank you for taking the time to talk with us today. We will be calling back in a month or so to ask you some additional questions. We appreciate your assistance.

End time of call _____

Appendix 11

FOLLOW-UP ASSESSMENT TOOL – 2-6 Months

ECRF _____ Today's Date _____ Initial Survey Date _____ Start time of call _____

First Name _____ Last Name _____

Address_____ City _____ State ___ Zip Code_____

Subject ID: _____ Subject's Age _____ Subject's Race _____

Breast Cancer _____ Ovarian Cancer _____ Both_____

CIS Introduction: "Hello, may I speak to _____. (IF PERSON IS THERE, CONTINUE; IF NOT CALL BACK OR RESCHEDULE CALL). My name is _____ and I am a representative of the Fox Chase Cancer Center. I am calling as a follow up to a phone call you made to the Cancer Information Service. When you called the CIS, a few weeks ago, you agreed to participate in a study that examines different approaches to providing information to women about breast cancer risk, risk assessment/genetic testing. To help us evaluate our service, we would like to ask you to participate in a brief, 10 minute, interview which will assess your specific thoughts, feelings, and behaviors concerning your genetic risk for breast/ovarian cancer."

"Would now be a good time to ask you a few questions?"

___YES → move to Questions

___ NO → reschedule call

"When would you like to reschedule this interview?"

Day: _____ Time: _____

Follow-up Assessment Tool: "We would just like to ask you a few questions about your thoughts and feeling concerning risk assessment/genetic testing".

1) a.) In your opinion, compared to other women your own age, what are your chances of getting breast cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

8	8	9
don't know	refused	missing

b.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8	9
don't know	refused	missing

2) a.) In your opinion, compared to other women your age who have a close relative with breast cancer, what are your chances of getting breast cancer some day?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

9	8	9
don't know	refused	missing

b.) How about ovarian cancer?

1	2	3	4	5
very much lower than average	somewhat lower than average	average	somewhat higher than average	much higher than average

7	8	9
don't know	refused	missing

3) a.) During the past month, how often have you thought about your own chances of getting breast cancer (again)? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

b.)How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

7) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your mood? Would you say… **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

b.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

8) a.) During the past month, how often have thoughts about your chances of getting breast cancer (again) affected your ability to perform your daily activities? Would you say... **[READ LIST]**

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

b.) How about ovarian cancer?

Not at all or rarely.....1
Sometimes.....2
Often.....3
A lot.....4

To what degree would you agree with the following statements:

6. Risk assessment/genetic testing can help you better understand your risk for breast/ovarian cancer, so that you can make decisions about pursuing risk reduction approaches, such as surgery and/or medications (e.g., tamoxifen)?

1	2	3	4
strongly disagree	mildly disagree	mildly agree	strongly agree

7. Risk assessment/genetic testing can help you better understand your risk for breast/ovarian cancer, so that you can determine if you need to increase screening, such as mammography or transvaginal ultrasounds.

1	2	3	4
strongly disagree	mildly disagree	mildly agree	strongly agree

8. Risk assessment/genetic testing can jeopardize your insurance coverage?

1	2	3	4
strongly disagree	mildly disagree	mildly agree	strongly agree

9. Risk assessment/genetic testing can have a negative emotional impact on you and on your family?

1	2	3	4
strongly disagree	mildly disagree	Mildly agree	strongly agree

10. Breast Cancer Heredity Knowledge Scale: Please answer true or false to the following questions.

	True	False	Don't know	Refused	Missing
Many women who do not have any of the known risk factors still get breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Over a lifetime, 1 out of 8 women will develop breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Women who are over 50 years of age are more likely to get breast cancer than are younger women	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Early detection means a greater chance of surviving breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Women over age 40 should have mammograms at least every two years	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman whose mother was diagnosed with breast cancer at age 69 is considered to be at high familial risk for breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman can inherit breast cancer gene mutations from her father	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Most women who develop breast cancer do not have a family history of the disease	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Ovarian cancer and breast cancer in the same family can be a sign of hereditary cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Testing for breast cancer gene mutations can tell a woman if she has breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
Men cannot inherit breast cancer gene mutations	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9

If there are other types of cancer in my family, I may have a higher than average risk of developing breast or ovarian cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
The process of risk assessment/genetic testing is simple, involving only a physical exam and blood test	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
One of the advantages of risk assessment/genetic testing is that, finding out your risk can help you make decisions about pursuing risk reduction options, such as surgery and medications	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
There are no real disadvantages to pursuing risk assessment/genetic testing	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who doesn't have an altered BRCA1 gene can still get cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9
A woman who develops breast cancer at an early age is more likely to have inherited breast cancer	☐ 1	☐ 2	☐ 7	☐ 8	☐ 9

11. At this point, how would you rate your knowledge about breast and ovarian cancer risks and the process involved in undergoing risk assessment/genetic testing for breast and ovarian cancer?

1. Very knowledgeable
2. Somewhat knowledgeable
3. Not very knowledgeable
4. Not at all knowledgeable

12. How would you describe your present behavior with regard to risk assessment and genetic testing for breast and ovarian cancer?

1. I have undergone risk assessment and genetic testing in the past 6 months (go to question 14)
2. I am planning to undergo risk assessment and genetic testing in the next 30 days
3. I am planning to undergo risk assessment and genetic testing in the next 6 months
4. I am thinking about undergoing risk assessment and genetic testing, but I'm not really sure and have made no specific plan
5. I am not thinking about undergoing risk assessment and genetic testing

13. If you were given the opportunity to pursue risk assessment/genetic testing, how prepared would you be to undergo these procedures?

1	2	3	4

not at all prepared	somewhat prepared	quite prepared	very prepared

14. How prepared did you feel when you under went these procedures?

1	2	3	4
not at all prepared	somewhat prepared	quite prepared	very prepared

15. How satisfied do you feel with the information you received on the phone from the CIS?

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

Why or why not _____

_____

_____

16. How satisfied do you feel with the information you received by mail from the CIS?

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

Why or why not _____

_____

_____

17. To what extent would you recommend that others contact the Cancer Information Services for this information?

definitely not	Probably not	maybe	probably	definitely
1	2	3	4	5

Why or why not _____

_____

_____

18. Has the information you received from the Cancer Information Service changed your thinking in regards to your personal risk for breast/ovarian? YES No

If YES. In what way?_____

_____

19. Has the information you received from the Cancer Information affected your decision to pursue risk assessment/genetic testing? YES No

If YES. In what way?_____

_____

20. Have you looked for more information on breast/ovarian cancer or risk assessment/genetic testing, since your call to the Cancer Information Service? YES NO

If YES. Where?

_____

21. Is there any information that you are now aware of that you wish you had received during your call to the Cancer Information Service? YES NO

If YES. What is that information?_____

_____

22. Have you discussed your family history with other family members? YES NO

23. Have you attempted to locate your family members medical records in order to confirm diagnosis?
YES NO

24. Have you discussed your concerns about cancer with your health care provider?
(1) ☐ Yes (2) ☐ No

25. How often do you perform Breast Self Exam (BSE)?

____ more than once a week
____ at least once a week
____ a couple of times a month
____ at least once a month
____ a few times each year
____ at least once a year
____ almost never
____ never

26. How often do you go for mammograms?

____ once every few months
____ a couple of times each year
____ once a year
____ once every few years
____ almost never
____ never

27. **(For ovarian cancer callers only):** In the past six months:
How many transvaginal ultrasounds have you had? _____
How many pelvic exams have you had? _____
How many CA 125 blood test have you had? _____

(2-Month Follow-Up) *In a few months, we will be calling one last time. The interview will be very brief. We thank you for helping with this research project.*

(6-Month Follow-Up) *Thank you for taking the time to talk with us today. This interview concludes your participation in this research study. We appreciate your assistance. Thank you for your participation.*

End time of call _____